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# OFFICE OF HEALTH MAINTENANCE ORGANIZATIONS

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# POLICY MANUAL

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U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

Public Health Service

Office of Health Maintenance Organizations

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# POLICY MANUAL

## Office of Health Maintenance Organizations

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# SECTION I

## Introduction

# OHMO POLICY MANUAL

## Introduction

Title XIII of the Public Health Service Act, (the Act), "Health Maintenance Organizations," was enacted by the Health Maintenance Organization Act of 1973, Pub. L. 93-222 and was amended in 1976 (by Pub. L. 94-460) and in 1978 (by Pub. L. 95-559). During the course of the administration of Title XIII by the Office of Health Maintenance Organizations, (OHMO), HMOs, employers, insurance companies, and health care administrators, among others, have identified questions relating to the requirements for federally qualified HMOs. The purpose of the Policy Manual is to unify in a single document: (1) the Act; (2) the regulations implementing Title XIII; (3) answers to significant questions which have been raised, including interpretive rulings; and (4) technical assistance guidance papers. Additionally, OHMO will use the materials in this manual in performing its administrative and regulatory duties under Title XIII and its implementing regulations.

## Contents

The Act is current through the 1979 Amendments. The regulations' section sets forth the existing final regulations followed by pending proposed regulations governing Title XIII. The section with questions and answers contains a mixture of: (1) interpretations of the regulations; and (2) informational re-statements of current regulatory language in the form of questions and answers. The final section, guidance papers, offers suggestions to persons and organizations seeking assistance in meeting the requirements of the Act and regulations. While the papers describe acceptable approaches, they do not mandate these approaches.

The materials set forth here as questions and answers and technical assistance guidance papers relate only to Subpart A of the HMO regulations. However, OHMO intends to issue further questions and answers and guidance papers, as appropriate, which relate to other subparts of the Title XIII regulations, as well as to update the materials regarding Subpart A.

## Format

The materials which constitute the OHMO Policy Manual are intended to fit into a standard three-ring binder.

The Act and regulations are reprinted verbatim. The questions and answers are set out in the following format:

1. The citation to the relevant section of the regulation and a brief statement of the general topic covered constitute the title to each page;
2. The regulatory language is stated;
3. A specific question is asked and the OHMO response follows, constituting the interpretive ruling; and
4. The date of the issuance is noted in the lower right-hand corner of each page.

For the technical assistance guidance papers:

1. The citation to the relevant section of the regulation and a brief statement of the general topic covered constitute the title to each page;
2. The regulatory language is stated;
3. The guidance paper then follows; and
4. The date of issuance is noted in the lower right-hand corner of each page.

## Distribution

The manual is available for distribution free of charge. Persons or organizations requesting the manual should write to:

Office of the Director
Office of Health Maintenance
Organizations
Park Building - 3rd Floor
12420 Parklawn Drive
Rockville, Maryland 20857

Any comments or questions on the material in the manual may also be directed to the above address. Your comments are welcomed.

# SECTION II

## Title XIII of the Public Health Service Act as amended

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# TITLE XIII—HEALTH MAINTENANCE ORGANIZATIONS 1/

## REQUIREMENTS FOR HEALTH MAINTENANCE ORGANIZATIONS

42 U.S.C. 300e

SEC. 1301. (a) For purposes of this title, the term "health maintenance organization" means a legal entity which (1) provides basic and supplemental health services to its members in the manner prescribed by subsection (b), and (2) is organized and operated in the manner prescribed by subsection (c).

(b) A health maintenance organization shall provide, without limitations as to time or cost other than those prescribed by or under this title, basic and supplemental health services to its members in the following manner:

(1) Each member is to be provided basic health services for a basic health services payment which (A) is to be paid on a periodic basis without regard to the dates health services (within the basic health services) are provided; (B) is fixed without regard to the frequency, extent, or kind of health service (within the basic health services) actually furnished; (C) except in the case of basic health services provided a member who is a full-time student (as defined by the Secretary) at an accredited institution of higher education, is fixed under a community rating system; and (D) may be supplemented by additional nominal payments which may be required for the provision of specific services (within the basic health services), except that such payments may not be required where or in such a manner that they serve (as determined under regulations of the Secretary) as a barrier to the delivery of health services. Such additional nominal payments shall be fixed in accordance with the regulations of the Secretary. A health maintenance organization may include a health service, defined as a supplemental health service by section 1302(2), in the basic health services provided its members for a basic health services payment described in the first sentence. In the case of an entity which before it became a qualified health maintenance organization (within the meaning of section 1310(d)) provided comprehensive health services on a prepaid basis, the requirement of clause (C) shall not apply to such entity until the expiration

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1/ This copy of Title XIII is an excerpt from the Compilation of Selected Acts Within the Jurisdiction of the Committee of Interstate and Foreign Commerce: Volume I, Health Law published in 1979.

of the forty-eight month period beginning with the month following the month in which the entity became such a qualified health organization. The requirements of this paragraph respecting the basic health services payment shall not apply to the provision of basic health services to a member for an illness or injury for which the member is entitled to benefits under a workmen's compensation law or an insurance policy but only to the extent such benefits apply to such services. For the provision of such services for an illness or injury for which a member is entitled to benefits under such a law, the health maintenance organization may, if authorized by such law, charge or authorize the provider of such services to charge, in accordance with the charges allowed under such law, the insurance carrier, employer, or other entity which under such law is to pay for the provision of such services or, to the extent that such member has been paid under such law for such services, such member. For the provision of such services for an illness or injury for which a member is entitled to benefits under an insurance policy, a health maintenance organization may charge or authorize the provider of such services to charge the insurance carrier under such policy or, to the extent that such member has been paid under such policy for such services, such member.

(2) For such payment or payments (hereinafter in this title referred to as "supplemental health services payments") as the health maintenance organization may require in addition to the basic health services payment, the organization may provide to each of its members any of the health services which are included in supplemental health services (as defined in section 1302(2)). Supplemental health services payments which are fixed on a prepayment basis shall be fixed under a community rating system unless the supplemental health services payment is for a supplemental health service provided a member who is a full-time student (as defined by the Secretary) at an accredited institution of higher education, except that, in the case of an entity which before it became a qualified health maintenance organization (within the meaning of section 1310(d)) provided comprehensive health services on a prepaid basis, the requirement of this sentence shall not apply to such entity during the forty-eight month period beginning with the month following the month in which the entity became such a qualified health maintenance organization.

(3)(A) Except as provided in subparagraph (B), the services of a physician which are provided as basic health services shall be provided through—

(i) members of the staff of the health maintenance organization,

(ii) a medical group (or groups),

(iii) an individual practice association (or associations),

(iv) subject to subparagraph (C), physicians or other health professionals who have contracted with the health maintenance organization for the provision of such services, or

(v) any combination of such staff, medical group (or groups), individual practice association (or associations) or physicians or other health professionals under contract with the organization.

(B)(i) Subparagraph (A) does not apply to the provision of the services of a physician—

(I) which the health maintenance organization determines, in conformity with regulations of the Secretary, are unusual or infrequently used, or

(II) which are provided a member of the organization in a manner other than that prescribed by subparagraph (A) because of an emergency which made it medically necessary that the service be provided to the member before it could be provided in a manner prescribed by subparagraph (A).

(ii) In a forty-eight-month period beginning after the month in which a health maintenance organization becomes a qualified health maintenance organization (within the meaning of section 1310(d)), the organization may provide the services of physicians through an entity which but for the requirement of section 1302(4)(C)(i) would be a medical group for the purposes of this title. After the expiration of such period, the organization may provide physician services through such an entity only if authorized by the Secretary in accordance with regulations which take into consideration the unusual circumstances of such entity.

(C) After the expiration of the first four fiscal years of a health maintenance organization beginning after the month in which it became a qualified health maintenance organization (within the meaning of section 1310(d)), the organization may not enter into contracts with physicians other than members of staff, medical groups, or individual practice associations if the amounts paid under such contracts for basic and supplemental health services provided by physicians exceed 15 per centum of the total estimated amount to be paid in such fiscal year by the health maintenance organization to physicians for the provision of basic and supplemental health services by physicians, or, if the health maintenance organization principally serves a rural area, 30 per centum of such amount, except that this subparagraph does not apply to the entering into contracts for the purchase of physician services through an entity which, but for the requirements of section 1302(4)(C)(i), would be a medical group for the purposes of this title.

(D) Contracts between a health maintenance organization and health professionals for the provision of basic and supplemental health services shall include such provisions as the Secretary may require (including provisions requiring appropriate continuing education).

(E) For purposes of this paragraph the term "health professional" means physicians, dentists, nurses, podiatrists, optometrists, and such other individuals engaged in the delivery of health services as the Secretary may by regulation designate.

(4) Basic health services (and only such supplemental health services as members have contracted for) shall within the area served by the health maintenance organization be available and accessible to each of its members promptly as appropriate and in a manner which assures continuity, and when medically necessary be available and accessible twenty-four hours a day and seven days a week. A member of a health maintenance organization shall be reimbursed by the organization for his expenses in securing basic and supplemental health services other than through the organization if the services were medically necessary and immediately required because of an unforeseen illness, injury, or condition.

(5) To the extent that a natural disaster, war, riot, civil insurrection, or any other similar event not within the control of a health maintenance organization (as determined under regulations of the Secretary) results in the facilities, personnel, or financial resources of a health maintenance organization not being available to provide or arrange for the provision of a basic or supplemental health service in accordance with the requirements of paragraphs (1) through (4) of this subsection, such requirements only require the organization to make a good-faith effort to provide or arrange for the provision of such service within such limitation on its facilities, personnel, or resources.

(c) Each health maintenance organization shall—

(1)(A) have a fiscally sound operation and adequate provision against the risk of insolvency which is satisfactory to the Secretary, and (B) have administrative and managerial arrangements satisfactory to the Secretary;

(2) assume full financial risk on a prospective basis for the provision of basic health services, except that a health maintenance organization may obtain insurance or make other arrangements (A) for the cost of providing to any member basic health services the aggregate value of which exceeds $5,000 in any year, (B) for the cost of basic health services provided to its members other than through the organization because medical necessity required their provision before they could be secured through the organization, and (C) for not more than 90 per centum of the amount by which its costs for any of its fiscal years exceed 115 per centum of its income for such fiscal year;

(3)(A) enroll persons who are broadly representative of the various age, social, and income groups within the area it serves, except that in the case of a health maintenance organization which has a medically underserved population located (in whole or in part) in the area it serves, not more than 75 per centum of the members of that organization may be enrolled from the medically underserved population unless the area in which such population resides is also a rural area (as designated by the Secretary), and (B) carry out enrollment of members who are entitled to medical assistance under a State plan approved under title XIX of the Social Security Act in accordance with procedures approved under regulations promulgated by the Secretary;

(4) have an open enrollment period in accordance with the provisions of subsection (d);

(5) not expel or refuse to re-enroll any member because of his health status or his requirements for health services;

(6)(A) in the case of a private health maintenance organization, be organized in such a manner that assures that (i) at least one-third of the membership of the policymaking body of the health maintenance organization will be members of the organization, and (ii) there will be equitable representation on such body of members from medically underserved populations served by the organization, and (B) in the case of a public health maintenance organization, have an advisory board to the policymaking body of the public entity operating the organization which board meets the requirements of clause (A) of this paragraph and to which may be delegated policymaking authority for the organization;

(7) be organized in such a manner that provides meaningful procedures for hearing and resolving grievances between the health maintenance organization (including the medical group or groups and other health delivery entities providing health serv-

ices for the organization) and the members of the organization;

(8) have organizational arrangements, established in accordance with regulations of the Secretary, for an ongoing quality assurance program for its health services which program (A) stresses health outcomes, and (B) provides review by physicians and other health professionals of the process followed in the provision of health services;

(9) provide medical social services for its members and encourage and actively provide for its members health education services, education in the appropriate use of health services, and education in the contribution each member can make to the maintenance of his own health;

(10) provide, or make arrangements for, continuing education for its health professional staff; and

(11) provide, in accordance with regulations of the Secretary (including safeguards concerning the confidentiality of the doctor-patient relationship), an effective procedure for developing, compiling, evaluating, and reporting to the Secretary, statistics and other information (which the Secretary shall publish and disseminate on an annual basis and which the health maintenance organization shall disclose, in a manner acceptable to the Secretary, to its members and the general public) relating to (A) the cost of its operations, (B) the patterns of utilization of its services, (C) the availability, accessibility, and acceptability of its services, (D) to the extent practical, developments in the health status of its members, and (E) such other matters as the Secretary may require.

(d)(1)(A) A health maintenance organization which—

(i) has for at least 5 years provided comprehensive health services on a prepaid basis, or

(ii) has an enrollment of at least 50,000 members,

shall have at least once during each fiscal year next following a fiscal year in which it did not have a financial deficit an open enrollment period (determined under subparagraph (B)) during which it shall accept individuals for membership in the order in which they apply for enrollment and, except as provided in paragraph (2), without regard to preexisting illness, medical condition, or degree of disability.

(B) An open enrollment period for a health maintenance organization shall be the lesser of—

(i) 30 days, or

(ii) the number of days in which the organization enrolls a number of individuals at least equal to 3 percent of its total net increase in enrollment (if any) in the fiscal year preceding the fiscal year in which such period is held.

For the purpose of determining the total net increase in enrollment in a health maintenance organization, there shall not be included any individual who is enrolled in the organization through a group which had a contract for health care services with the health maintenance organization at the time that such health maintenance organization was determined to be a qualified health maintenance organization under section 1310.

(2) Notwithstanding the requirements of paragraph (1) a health maintenance organization shall not be required to enroll individuals who are confined to an institution because of chronic illness, permanent injury, or other infirmity which would cause economic impairment to the health maintenance organization if such individual were enrolled.

(3) A health maintenance organization may not be required to make the effective date of benefits for individuals enrolled under this subsection less than 90 days after the date of enrollment.

(4) The Secretary may waive the requirements of this subsection for a health maintenance organization which demonstrates that compliance with the provisions of this subsection would jeopardize its economic viability in its service area.

### DEFINITIONS

SEC. 1302. For purposes of this title: 42 U.S.C. 300e–1

(1) The term "basic health services" means—

(A) physician services (including consultant and referral services by a physician);

(B) inpatient and outpatient hospital services;

(C) medically necessary emergency health services;

(D) short-term (not to exceed twenty visits), outpatient evaluative and crisis intervention mental health services;

(E) medical treatment and referral services (including referral services to appropriate ancillary services) for the abuse of or addiction to alcohol and drugs;

(F) diagnostic laboratory and diagnostic and therapeutic radiologic services;

(G) home health services; and

(H) preventive health services (including (i) immunizations, (ii) well-child care from birth, (iii) periodic health evaluations for adults, (iv) voluntary family planning services, (v) infertility services, and (vi) children's eye and ear examinations conducted to determine the need for vision and hearing correction).

Such term does not include a health service which the Secretary, upon application of a health maintenance organization, determines is unusual and infrequently provided and not necessary for the protection of individual health. The Secretary shall publish in the Federal Register each determination made by him under the preceding sentence. If a service of a physician described in the preceding sentence may also be provided under applicable State law by a dentist, optometrist, podiatrist, or other health care personnel a health maintenance organization may provide such service through a dentist, optometrist, podiatrist, or other health care personnel (as the case may be) licensed to provide such service. For purposes of this paragraph, the term "home health services" means health services provided at a member's home by health care personnel, as prescribed or directed by the responsible physician or other authority designated by the health maintenance organization. A health maintenance organization is authorized, in connection with the prescription of drugs, to maintain, review, and evaluate (in accordance with regulations of the Secretary) a drug use profile of its members receiving such service, evaluate patterns of drug utilization to assure optimum drug therapy, and provide for instruction of its members and of health professionals in the use of prescription and non-prescription drugs.

(2) The term "supplemental health services" means—

(A) services of facilities for intermediate and long-term care;

(B) vision care not included as a basic health service;

(C) dental services not included as a basic health service;

(D) mental health services not included as a basic health service under paragraph (1)(D);

(E) long-term physical medicine and rehabilitative services (including physical therapy);

(F) the provision of prescription drugs prescribed in the course of the provision by the health maintenance organization of a basic health service or a service described in the preceding subparagraphs of this paragraph; and

(G) other health services which are not included as basic health services and which have been approved by the Secretary for delivery as supplemental health services.

If a service of a physician described in the preceding sentence may also be provided under applicable State law by a dentist, optometrist, podiatrist, or other health care personnel, a health maintenance organization may provide such service through an optometrist, dentist, podiatrist, or other health care personnel (as the case may be) licensed to provide such service. A health maintenance organization is authorized, in connection with the prescription or provision of prescription drugs, to maintain, review, and evaluate (in accordance with regulations of the Secretary) a drug use profile of its members receiving such services, evaluate patterns of drug utilization to assure optimum drug therapy, and provide for instruction of its members and of health professionals in the use of prescription and non-prescription drugs.

(3) The term "member" when used in connection with a health maintenance organization means an individual who has entered into a contractual agreement, or on whose behalf a contractual arrangement has been entered into, with the organization under which the organization assumes the responsibility for the provision to such individual of basic health services and of such supplemental health services as may be contracted for.

(4) The term "medical group" means a partnership, association, or other group—

(A) which is composed of health professionals licensed to practice medicine or osteopathy and of such other licensed health professionals (including dentists, optometrists, and podiatrists) as are necessary for the provision of health services for which the group is responsible;

(B) a majority of the members of which are licensed to practice medicine or osteopathy; and

(C) the members of which (i) as their principal professional activity engage in the coordinated practice of their profession and as a group responsibility have substantial responsibility for the delivery of health services to members of a health maintenance organization; (ii) pool their income from practice as members of the group and distribute it among themselves according to a prearranged salary or drawing account or other similar plan unrelated to the provision of specific health services; (iii) share medical and other records and substantial portions of major equipment and of professional, technical, and administrative staff; (iv) arrange for and encourage continuing education in the field of clinical medicine and related areas for the members of the group; and (v) establish an arrangement whereby a member's enrollment status is not known to the health professional who provides health services to the member.

(5) The term "individual practice association" means a partnership, corporation, association, or other legal entity which has entered into a services arrangement (or arrangements) with persons who are licensed to practice medicine, osteopathy, dentistry, podiatry, optometry, or other health profession in a State and a majority of whom are licensed to practice medicine or osteopathy. Such an arrangement shall provide—

(A) that such persons shall provide their professional services in accordance with a compensation arrangement established by the entity; and

(B) to the extent feasible (i) for the sharing by such persons of medical and other records, equipment, and professional, technical, and administrative staff, and (ii) for the arrangement and encouragement of the continuing education of such persons in the field of clinical medicine and related areas.

(6) The term "health systems agency" means an entity which is designated in accordance with section 1515 of this Act.

(7) The term "medically underserved population" means the population of an urban or rural area designated by the Secretary as an area with a shortage of personal health services or a population group designated by the Secretary as having a shortage of such services. Such a designation may be made by the Secretary only after consideration of the comments (if any) of (A) each State health planning and development agency which covers (in whole or in part) such urban or rural area or the area in which such population group resides, and (B) each health systems agency designated for a health service area which covers (in whole or in part) such urban or rural area or the area in which such population group resides.

(8) The term "community rating system" means a system of fixing rates of payments for health services. Under such a system rates of payments may be determined on a per-person or per-family basis and may vary with the number of persons in a family, but except as otherwise authorized in the next sentence, such rates must be equivalent for all individuals and for all families of similar composition. The following differentials in rates of payments may be established under such system:

(A) Nominal differentials in such rates may be established to reflect differences in marketing costs and the different administrative costs of collecting payments from the following categories of members:

(i) Individual members (including their families).

(ii) Small groups of members (as determined under regulations of the Secretary).

(iii) Large groups of members (as determined under regulations of the Secretary).

(B) Nominal differentials in such rates may be established to reflect the compositing of the rates of payment in a systematic manner to accommodate group purchasing practices of the various employers.

(C) Differentials in such rates may be established for members enrolled in a health maintenance organization pursuant to a contract with a govermental authority under section 1079 or 1086 of title 10, United States Code, or under any other governmental program (other than the health benefits program authorized by chapter 89 of title 5, United States Code) or any health benefits program for employees of States, political subdivision of States, and other public entities.

(9) The term "non-metropolitan area" means an area no part of which is within an area designated as a standard metropolitan statistical area by the Office of Management and Budget and which does not contain a city whose population exceeds fifty thousand individuals.

### GRANTS AND CONTRACTS FOR FEASIBILITY SURVEYS

SEC. 1303. (a) The Secretary may make grants to and enter into contracts with public or nonprofit private entities for projects for surveys or other activities to determine the feasibility of developing and operating or expanding the operation of health maintenance organizations. 42 U.S.C. 300e-2

(b) An application for a grant or contract under this section shall contain—

(1) assurances satisfactory to the Secretary that, in conducting surveys or other activities with assistance under a grant or contract under this section, the applicant will (A) cooperate with each health systems agency designated for a health service area which covers (in whole or in part) the area for which the survey or other activity will be conducted, and (B) notify the medical society serving such area of such surveys or other activities; and

(2) such other information as the Secretary may by regulation prescribe.

(c) In considering applications for grants and contracts under this section, the Secretary shall give priority to an application which contains or is supported by assurances satisfactory to the Secretary that at the time the health maintenance organization for which such application or proposal is submitted first becomes operational not less than 30 per centum of its members will be members of a medically underserved population.

(d)(1) Except as provided in paragraph (2), the following limitations apply with respect to grants and contracts made under this section:

(A) If a project has been assisted with a grant or contract under subsection (a), the Secretary may not make any other grant or enter into any other contract under this section for such project.

(B) Any project for which a grant is made or contract entered into must be completed within twelve months from the date the grant is made or contract entered into.

(2) The Secretary may make not more than one additional grant or enter into not more than one additional

contract for a project for which a grant has previously been made or a contract previously entered into, and he may permit additional time (up to twelve months) for completion of the project if he determines that the additional grant or contract (as the case may be), or additional time, or both, is needed to adequately complete the project.

(e) The amount to be paid by the United States under a grant made, or contract entered into, under subsection (a) shall be determined by the Secretary, except that (1) the amount to be paid by the United States under any single grant or contract for any project may not exceed $75,000, and (2) the aggregate of the amounts to be paid by the United States for any project under such subsection under grants or contracts, or both, may not exceed the greater of (A) 90 per centum of the costs of such project (as determined under regulations of the Secretary), or (B) in the case of a project for a health maintenance organization which will serve a medically underserved population, such greater percentage (up to 100 per centum) of such cost as the Secretary may prescribe if he determines that the ceiling on the grants and contracts for such project should be determined by such greater percentage.

(f) Payments under grants under this section may be made in advance or by way of reimbursement and at such intervals and on such conditions as the Secretary finds necessary.

(g) Contracts may be entered into under this section without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529; 41 U.S.C. 5).

(h) Payments under grants and contracts under this section shall be made from appropriations made under section 1309(a).

(i) Of the sums appropriated for any fiscal year under section 1309(a) for grants and contracts under this section, not less than 20 per centum shall be set aside and obligated in such fiscal year for projects (1) to determine the feasibility of developing and operating or expanding the operation of health maintenance organizations which the Secretary determines may reasonably be expected to have after their development or expansion not less than 66 per centum of their membership drawn from residents of non-metropolitan areas, and (2) the applications for which meet the requirements of this title for approval. Sums set aside in any fiscal year for projects described in the preceding sentence but not obligated in such fiscal year for grants and contracts under this section because of a lack of applicants for projects meeting the requirements of such sentence shall remain available for obligation under this section in the succeeding fiscal year for any project, with priority being given to projects described in clause (1) of such sentence.

## GRANTS, CONTRACTS, AND LOAN GUARANTEES FOR PLANNING AND FOR INITIAL DEVELOPMENT COSTS

42 U.S.C. 300e–3

SEC. 1304. (a) The Secretary may—

(1) make grants to and enter into contracts with public or nonprofit private entities for planning projects for the establishment of health maintenance organizations or for the significant expansion of the membership of, or areas served by, health maintenance organizations; and

(2) guarantee to non-Federal lenders payment of the principal of and the interest on loans made to—

(A) nonprofit private entities for planning projects for the establishment or expansion of health maintenance organizations, or

(B) other private entities for such projects for health maintenance organizations which will serve medically underserved populations.

Planning projects assisted under this subsection shall include development of plans for the marketing of the services of the health maintenance organization.

(b) (1) The Secretary may—

(A) make grants to and enter into contracts with public or nonprofit private entities for projects for the initial development of health maintenance organizations; and

(B) guarantee to non-Federal lenders payment of the principal of and the interest on loans made to—

(i) nonprofit private entities for projects for the initial development of health maintenance organizations, or

(ii) other private entities for such projects for health maintenance organizations which will serve medically underserved populations.

(2) For purposes of this section, the term "initial development" when used to describe a project for which assistance is authorized by this subsection means the establishment of a health maintenance organization, the expansion of the services of a health maintenance organization, or the significant expansion of the membership of, or the area served by, a health maintenance organization. Funds under grants and contracts under this subsection and under loans guaranteed under this subsection may only be utilized for such purposes as the Secretary may prescribe in regulations. Such purposes may include (A) the implementation of an enrollment campaign for such an organization, (B) the detailed design of and arrangements for the health services to be provided by such an organization, (C) the development of administrative and internal organizational arrangements, including fiscal control and fund accounting procedures, and the development of a capital financing program, (D) the recruitment of personnel who will engage in practice principally for the health maintenance organization and the conduct

of training activities for such personnel, and (E) the payment of architects' and engineers' fees.

(3) A grant or contract under this subsection may only be made or entered into for initial development costs incurred in a period not to exceed three years from the first day of the first month in which such grant or contract is made or entered into. A loan guarantee under this subsection may only be made for a loan (or loans) for such costs incurred in a period not to exceed three years.

(4) A health maintenance organization which is a qualified health maintenance organization within the meaning of section 1310(d) may receive, in accordance with paragraph (1), a grant, contract, or loan guarantee for the expansion of its services or the significant expansion of its membership or the area served by it.

(c)(1) An application for a grant, contract, or loan guarantee under subsection (a) for a planning project shall contain assurances satisfactory to the Secretary that in carrying out the planning project for which the grant, contract, or loan guarantee is sought, the applicant will (A) cooperate with each health systems agency designated for a health service area which covers (in whole or in part) the area proposed to be served by the health maintenance organization for which the planning project will be conducted, and (B) notify the medical society serving such area of the planning project.

(2) If the Secretary makes a grant or loan guarantee or enters into a contract under subsection (a) for a planning project for a health maintenance organization, he may, within the period in which the planning project must be completed, make a grant or loan guarantee or enter into a contract under subsection (b) for the initial development of that health maintenance organization; but no grant or loan guarantee may be made or contract entered into under subsection (b) for initial development of a health maintenance organization unless the Secretary determines that (A) sufficient planning for its establishment or expansion (as the case may be) has been conducted by the applicant for the grant, contract, or loan guarantee, and (B) the feasibility of establishing and operating, or of expanding, the health maintenance organization has been established by the applicant.

(d) In considering applications for grants and contracts under this section, the Secretary shall give priority to an application which contains or is supported by assurances satisfactory to the Secretary that at the time the health maintenance organization for which such application is submitted first becomes operational not less than 30 per centum of its members will be members of a medically underserved population. In considering applications for loan guarantees under this section, the Secretary shall give special consideration to applications for projects for health maintenance organizations which will serve medically underserved populations.

(e)(1) Except as provided in paragraph (2), the following limitations apply with respect to grants, loan guarantees, and contracts made under subsection (a) of this section:

(A) If a planning project has been assisted with grant, loan guarantee, or contract under subsection (a), the Secretary may not make any other planning grant or loan guarantee or enter into any other planning contract for such project under this section.

(B) Any project for which a grant or loan guarantee is made or contract entered into must be completed within twelve months from the date the grant or loan guarantee is made or contract entered into.

(2) The Secretary may not make more than one additional grant or loan guarantee or enter into not more than one additional contract for a planning project for which a grant or loan guarantee has previously been made or a contract previously entered into, and he may permit additional time (up to twelve months) for completion of the project if he determines that the additional grant, loan guarantee, or contract (as the case may be), or additional time, or both, is needed to adequately complete the project.

(f)(1) The amount to be paid by the United States under a grant made, or contract entered into, under subsection (a) for a planning project, and (except as provided in paragraph (3) of this subsection) the amount of principal of a loan for a planing project which may be guaranteed under such subsection, shall be determined by the Secretary, except that (A) the amount to be paid by the United States under any single grant or contract, and the amount of principal of any single loan guaranteed under such subsection, may not exceed $200,000, and (B) the aggregate of the amounts to be paid for any project by the United States under grants or contracts, or both, under such subsection, and the aggregrate amount of principal of loans guaranteed under such subsection for any project, may not exceed the greater of (i) 90 per centum of the cost of such project (as determined under regulations of the Secretary), or (ii) in the case of a project for a health maintenance organization which will serve a medically underserved population, such greater percentage (up to 100 per centum) of such cost as the Secretary may prescribe if he determines that the ceiling on the grants, contracts, and loan guarantees (or any combination thereof) for such project should be determined by such greater percentage.

(2) Except as provided in paragraph (3), the amount to be paid by the United States under a grant made, or contract entered into, under subsection (b) for an initial development project, and the amount of principal of a loan for an initial development project which may be guaranteed under such subsection, shall be determined by the Secretary; except that the amounts to be paid by the

United States for any initial development project under grants or contracts, or both, under such subsection, and the aggregate amount of principal of loans guaranteed under such subsection for any project, may not exceed the lesser of—

(A) $1,000,000 through September 30, 1979, and $2,000,000 thereafter, or

(B) an amount equal to the greater of (i) 90 per centum of the cost of such project (as determined under regulations of the Secretary), or (ii) in the case of a project for a health maintenance organization which will serve a medically underserved population, such greater percentage (up to 100 per centum) of such cost as the Secretary may prescribe if he determines that the ceiling on the grants, contracts, and loan guarantees (or any combination thereof) for such project should be determined by such greater percentage.

(3) The cumulative total of grants made to, contracts entered into with, and principal of loans guaranteed for, a health maintenance organization under subsection (b) of this section may not exceed $1,000,000 through September 30, 1979, or $2,000,000 thereafter. The cumulative total of the principal of the loans outstanding at any time with respect to which guarantees have been issued under this section may not exceed such limitations as may be specified in appropriation Acts.

(g) Payments under grants under this section may be made in advance or by way of reimbursement and at such intervals and on such conditions as the Secretary finds necessary.

(h) Contracts may be entered into under this section without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529; 41 U.S.C. 5).

(i) Payments under grants and contracts under this section shall be made from appropriations under section 1309(a).

(j) Loan guarantees under subsection (a)(2) for planning projects and loan guarantees under subsection (b)(1)(B) for initial development projects may be made through the fiscal year ending September 30, 1981.

(k)(1) Of the sums appropriated for any fiscal year under section 1309(a) for grants and contracts under subsection (a) of this section, not less than 20 per centum shall be set aside and obligated in such fiscal year for projects (A) to plan the establishment or expansion of health maintenance organizations which the Secretary determines may reasonably be expected to have after their establishment or expansion not less than 66 per centum of their membership drawn from residents of non-metropolitan areas, and (B) the applications for which meet the requirements of this title for approval. Sums set aside in any fiscal year for projects described in the preceding sentence but not obligated in such fiscal year for grants and contracts under subsection (a) of this section because of a lack of applicants for projects meeting the requirements of such sentence shall remain available for obligation under such subsection in the succeeding fiscal year for any project, with priority being given to projects described in clause (A) of such sentence.

(2) Of the sums appropriated for any fiscal year under section 1309(a) for grants and contracts under subsection (b) of this section, not less than 20 per centum shall be set aside and obligated in such fiscal year for projects (A) for the initial development of health maintenance organizations which the Secretary determines may reasonably be expected to have after their initial development not less than 66 per centum of their membership drawn from residents of non-metropolitan areas, and (B) the applications for which meet the requirements of this title for approval. Sums set aside in any fiscal year for projects described in the preceding sentence but not obligated in such fiscal year for grants and contracts under subsection (b) of this section because of a lack of applicants for projects meeting the requirements of such sentence shall remain available for obligation under such subsection in the succeeding fiscal year for any project, with priority being given to projects described in clause (A) of such sentence.

### LOANS AND LOAN GUARANTEES FOR INITIAL COSTS OF OPERATION

SEC. 1305. (a) The Secretary may— 42 U.S.C. 300e-4

(1) make loans to public or nonprofit private health maintenance organizations to assist them in meeting the amount by which their costs of operation during a period not to exceed the first sixty months of their operation exceed their revenues in that period;

(2) make loans to public or nonprofit private health maintenance organizations to assist them in meeting the amount by which their costs of operation, which the Secretary determines are attributable to significant expansion in their membership or area served and which are incurred during a period not to exceed the first sixty months of their operation after such expansion, exceed their revenues in that period which the Secretary determines are attributable to such expansion; and

(3) guarantee to non-Federal lenders payment of the principal of and the interest on loans made to—

(A) nonprofit private health maintenance organizations for the amounts referred to in paragraph (1) or (2), or

(B) other private health maintenance organizations for such amounts but only if the health maintenance organization will serve a medically underserved population.

No loan or loan guarantee may be made under this subsection for the costs of operation of a health maintenance organization unless the Secretary determines that the organization has made all reasonable attempts to meet such costs.

(b)(1) Except as provided in paragraph (2), the aggregate amount of principal of loans made or guaranteed, or both, under this section for a health maintenance organization may not exceed $2.500.000 (or $4,500,000 ~~$4,000,000~~ if the Secretary makes a written determination that such loans or loan guarantees are necessary to preserve the fiscally sound operation of the health maintenance organization and to protect against the risk of insolvency of the health maintenance organization and, within 30 days of the making of such loans or loan guarantees, furnishes the Committee on Human Resources of the Senate and the Committee on Interstate and Foreign Commerce of the House of Representatives with written notification of the making of the loans or loan guarantees and a copy of the written determination made with respect to the loans or loan guarantees and the reasons for the determination) through September 30, 1979, and $4,500,000 ~~$4,000,000~~ thereafter. In any twelve-month period the amount disbursed to a health maintenance organization under this section (either directly by the Secretary or by an escrow agent under the terms of an escrow agreement or by a lender under a loan guaranteed under this section) may not exceed $1.000.000 (or $2.000.000 if the Secretary makes a written determination that such disbursements are necessary to preserve the fiscally sound operation of the health maintenance organization and protect against the risk of insolvency of the health maintenance organization and, within 30 days of such disbursement, furnishes the Committee on Human Resources of the Senate and the Committee on Interstate and Foreign Commerce of the House of Representatives with written notification of the making of the disbursement and a copy of the written determination made with respect to it and the reasons for the determination) through September 30, 1979, and $2.000.000 thereafter.

(2) The cumulative total of the principal of the loans outstanding at any time which have been directly made or with respect to which guarantees have been issued under subsection (a) may not exceed such limitations as may be specified in appropriation Acts.

(c) Loans under this section shall be made from the fund established under section 1308(e).

(d) No loan may be made or guaranteed under this section after September 30, 1981.

(e) Of the sums used for loans under this section in any fiscal year from the loan fund established under section 1308(e), not less than 20 per centum shall be used for loans for projects (1) for the initial operation of health maintenance organizations which the Secretary determines have not less than 66 per centum of their membership drawn from residents of nonmetropolitan areas, and (2) the applications for which meet the requirements of this title for approval.

(f) In considering applications for loan guarantees under this section, the Secretary shall give special consideration to applications for health maintenance organizations which will serve medically underserved populations.

### LOANS AND LOAN GUARANTEES FOR ACQUISITION AND CONSTRUCTION OF AMBULATORY HEALTH CARE FACILITIES

Sec. 1305A. (a) The Secretary may— 42 U.S.C. 300e-4a

(1) make loans, from the fund established under section 1308(e), to public and nonprofit private health maintenance organizations for projects for the acquisition or construction of ambulatory health care facilities and for the acquisition of equipment for facilities acquired or constructed under a loan made under this paragraph; and

(2) guarantee to—

(A) non-Federal lenders for their loans to nonprofit private health maintenance organizations for projects described in paragraph (1) and to private health maintenance organizations for such projects which will serve medically underserved populations, and

(B) the Federal Financing Bank for its loans to nonprofit private health maintenance organizations for projects described in paragraph (1) and to private health maintenance organizations for such projects which will serve medically underserved populations,

the payment of principal and interest on such loans.

(b)(1) Except as provided in paragraph (2), the aggregate amount of principal of loans made or guaranteed, or both, under subsection (a) for an ambulatory health care facility may not exceed $2,500,000.

(2) The cumulative total of the principal of the loans outstanding at any time which have been directly made or with respect to which guarantees have been issued under subsection (a) may not exceed such limitations as may be specified in appropriation Acts.

(3) The authority of the Secretary to make loans under subsection (a) shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance in appropriation Acts.

(c) For purposes of this section—

(1) the ~~The~~ term "ambulatory health care facility" means a health care facility for the provision of diagnostic, treatment, and prevention services to ambulatory patients; and

(2) the term "construction" means the (A) construction of new facilities, (B) alterations, expansion, remodeling, replacement, and renovation of existing facilities, (C) cost of offsite improvements in connection with an activity described in clause (A) or (B), and (D) cost of the acquisition of land in connection with an activity described in clause (A), (B), or (C).

### APPLICATION REQUIREMENTS

42 U.S.C. 300e-5 Sec. 1306. (a) No grant, contract, loan, or loan guarantee may be made under this title unless an application therefor has been submitted to and approved by the Secretary.

(b) The Secretary may not approve an application for a grant, contract, loan, or loan guarantee under this title unless—

(1) in the case of an application for assistance under section 1303 or 1304, such application meets the application requirements of such section and in the case of an application for a loan or loan guarantee, such application meets the requirements of section 1308;

(2) in the case of an application for assistance under section 1304, 1305, or 1305A, he determines that the applicant making the application would not be able to complete the project or undertaking for which the application is submitted without the assistance applied for;

(3) the application contains satisfactory specification of the existing or anticipated (A) population group or groups to be served by the proposed or existing health maintenance organization described in the application, (B) membership of such organization, (C) methods, terms, and periods of the enrollment of members of such organization, (D) estimated costs per member of the health and educational services to be provided by such organization and the nature of such costs, (E) sources of professional services for such organization, and organizational arrangements of such organization for providing health and educational services, (F) organizational arrangements of such organization for an ongoing quality assurance program in conformity with the requirements of section 1301(c), (G) sources of prepayment and other forms of payment for the services to be provided by such organization, (H) facilities, and additional capital investments and sources of financing therefor, available to such orga-

nization to provide the level and scope of services proposed, (I) administrative, managerial, and financial arrangements and capabilities of such organization, (J) role for members in the planning and policymaking for such organization, (K) grievance procedures for members of such organization, and (L) evaluations of the support for and acceptance of such organization by the population to be served, the sources of operating support, and the professional groups to be involved or affected thereby;

(4) contains or is supported by assurances satisfactory to the Secretary that the applicant making the application will, in accordance with such criteria as the Secretary shall by regulation prescribe, enroll, and maintain an enrollment of the maximum number of members that its available and potential resources (as determined under regulations of the Secretary) will enable it to effectively serve·

(5) each health systems agency designated for a health service area which covers (in whole or in part) the area to be served by the health maintenance organization for which such application is submitted has, in accordance with regulations of the Secretary under subsection (c) of this section, been provided an opportunity to review the application and to submit to the Secretary for his consideration its recommendations respecting approval of the application or if under applicable State law such an application may not be submitted without the approval of the HSA, the required approval has been obtained;

(6) in the case of an application made for a project which previously received a grant, contract, loan, or loan guarantee under this title, such application contains or is supported by assurances satisfactory to the Secretary that the applicant making the application has the financial capability to adequately carry out the purposes of such project and has developed and operated such project in accordance with the requirements of this title and with the plans contained in previous applications for such assistance;

(7) the application contains such assurances as the Secretary may require respecting the intent and the ability of the applicant to meet the requirements of paragraphs (1) and (2) of section 1301(b) respecting the fixing of basic health services payments and supplemental health services payments under a community rating system; and

(8) the application is submitted in such form and manner, and contains such additional information, as the Secretary shall prescribe in regulations.

An organization making multiple applications for more than one grant, contract, loan, or loan guarantee under this title, simultaneously or over the course of time, shall not be required to submit duplicate or redundant information but shall be required to update the specifications (required by paragraph (3)) respecting the existing or proposed health maintenance organization in such manner and with such frequency as the Secretary may by regulation prescribe. In determining, for purposes of paragraph (2), whether an applicant would be able to complete a project or undertaking without the assistance applied for, the Secretary shall not consider any asset of the applicant the obligation of which for such undertaking or project would jeopardize the fiscal soundness of the applicant.

(c) The Secretary shall by regulation establish standards and procedures for health systems agencies to follow in reviewing and commenting on applications for grants, contracts, loans, and loan guarantees under this title.

### ADMINISTRATION OF ASSISTANCE PROGRAMS

42 U.S.C. 300e-6

Sec. 1307. (a) (1) Each recipient of a grant, contract, loan, or loan guarantee under this title shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of the grant, contract, or loan (directly made or guaranteed), the total cost of the undertaking in connection with which such assistance was given or used, the amount of that portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(2) The Secretary, or any of his duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipients of a grant, contract, loan, or loan guarantee under this title which relate to such assistance.

(b) Upon expiration of the period for which a grant, contract, loan, or loan guarantee was provided an entity under this title, such entity shall make a full and complete report to the Secretary in such manner as he may by regulation prescribe. Each such report shall contain, among such other matters as the Secretary may by regulation require, descriptions of plans, developments, and operations relating to the matters referred to in section 1306(b)(3).

(c) If in any fiscal year the funds appropriated under section 1309 are insufficient to fund all applications approved under this title for that fiscal year, the Secretary shall, after applying the applicable priorities under sections 1303 and 1304, give priority to the funding of applications for projects which the Secretary determines are the most likely to be economically viable.

(d) An entity which provides health services to a defined population on a prepaid basis and which has members who are entitled to insurance benefits under title XVIII of the Social Security Act or to medical assistance under a State plan approved under title XIX of such Act may be considered as a health maintenance organization for purposes of receiving assistance under this title if—

(1) with respect to its members who are entitled to such insurance benefits or to such medical assistance it (A) provides health services in accordance with section 1301(b), except that (i) it does not furnish to those members the health services (within the basic health services) for which it may not be compensated under such title XVIII or such State plan, and (ii) it does not fix the basic or supplemental health services payment for such members under a community rating system, and (B) is organized and operated in the manner prescribed by section 1301(c), except that it does not assume full financial risk on a prospective basis for the provision to such members of basic or supplemental health services with respect to which it is not required under such title XVIII or such State plan to assume such financial risk; and

(2) with respect to its other members it provides health services in accordance with section 1301(b) and is organized and operated in the manner prescribed by section 1301(c).

An entity which provides health services to a defined population on a prepaid basis and which has members who are enrolled under the health benefits program authorized by chapter 89 of title 5, United States Code, may be considered as a health maintenance organization for purposes of receiving assistance under this title if with respect to its other members it provides health services in accordance with section 1301(b) and is organized and operated in the manner prescribed by section 1301(c).

(e) In any fiscal year no loan guarantee may be made for a private health maintenance organization (other than a private nonprofit health maintenance organization) under this title if the making of such guarantee would cause the cumulative total of the principal of the loans guaranteed; for private health maintenance organizations (other than private nonprofit health maintenance organizations) under this title in such fiscal year to exceed the amount of grant and contract funds obligated under this title in such fiscal year; except that this subsection shall not apply if the amount of grant and contract funds obligated under this title in such fiscal year equals the sums appropriated under section 1309 for grants and contracts for such fiscal year.

### GENERAL PROVISIONS RELATING TO LOAN GUARANTEES AND LOANS

Sec. 1308. (a)(1) The Secretary may not approve an application for a loan guarantee under this title unless he determines that (A) the terms, conditions, security (if any), and schedule and amount of repayments with respect to the loan are sufficient to protect the financial interests of the United States and are otherwise reasonable, including a determination that the rate of interest does not exceed such per centum per annum on the principal obligation outstanding as the Secretary determines to be reasonable, taking into account the range of interest rates prevailing in the private market for loans with similar maturities, terms, conditions, and security and the risks assumed by the United States, and (B) the loan would not be available on reasonable terms and conditions without the guarantee under this title.

(2)(A) The United States shall be entitled to recover from the applicant for a loan guarantee under this title the amount of any payment made pursuant to such guarantee, unless the Secretary for good cause waives such right of recovery; and, upon making any such payment, the United States shall be subrogated to all of the rights of the recipient of the payments with respect to which the guarantee was made.

(B) To the extent permitted by subparagraph (C), any terms and conditions applicable to a loan guarantee under this title (including terms and conditions imposed under subparagraph (D)) may be modified by the Secretary to the extent he determines it to be consistent with the financial interest of the United States.

(C) Any loan guarantee made by the Secretary under this title shall be incontestable (i) in the hands of an applicant on whose behalf such guarantee is made unless the applicant engaged in fraud or misrepresentation in securing such guarantee, and (ii) as to any person (or his successor in interest) who makes or contracts to make a loan to such applicant in reliance thereon unless such person (or his successor in interest) engaged in fraud or misrepresentation in making or contracting to make such loan.

(D) Guarantees of loans under this title shall be subject to such further terms and conditions as the Secretary determines to be necessary to assure that the purposes of this title will be achieved.

(b)(1) The Secretary may not approve an application for a loan under this title unless—

(A) the Secretary is reasonably satisfied that the applicant therefor will be able to make payments of principal and interest thereon when due, and

(B) the applicant provides the Secretary with reasonable assurances that there will be available to it such additional funds as may be necessary to complete the project or undertaking with respect to which such loan is requested.

(2) Any loan made under this title shall (A) have such security, (B) have such maturity date, (C) be repayable in such installments, (D) bear interest at a rate comparable to the current rate of interest prevailing, on the date

the loan is made, with respect to marketable obligations of the United States of comparable maturities, adjusted to provide for appropriate administrative charges, and (E) be subject to such other terms and conditions (including provisions for recovery in case of default), as the Secretary determines to be necessary to carry out the purposes of this title while adequately protecting the financial interests of the United States.

(3) The Secretary may, for good cause but with due regard to the financial interests of the United States, waive any right of recovery which he has by reason of the failure of a borrower to make payments of principal of and interest on a loan made under this title, except that if such loan is sold and guaranteed, any such waiver shall have no effect upon the Secretary's guarantee of timely payment of principal and interest.

(c)(1) The Secretary may from time to time, but with due regard to the financial interests of the United States, sell loans made by him under this title.

(2) The Secretary may agree, prior to his sale of any such loan, to guarantee to the purchaser (and any successor in interest of the purchaser) compliance by the borrower with the terms and conditions of such loan. Any such agreement shall contain such terms and conditions as the Secretary considers necessary to protect the financial interests of the United States or as otherwise appropriate. Any such agreement may (A) provide that the Secretary shall act as agent of any such purchaser for the purpose of collecting from the borrower to which such loan was made and paying over to such purchaser, any payments of principal and interest payable by such organization under such loan; and (B) provide for the repurchase by the Secretary of any such loan on such terms and conditions as may be specified in the agreement. The full faith and credit of the United States is pledged to the payment of all amounts which may be required to be paid under any guarantee under this paragraph.

(3) After any loan under this title to a public health maintenance organization has been sold and guaranteed under this subsection, interest paid on such loan which is received by the purchaser thereof (or his successor in interest) shall be included in the gross income of the purchaser of the loan (or his successor in interest) for the purpose of chapter 1 of the Internal Revenue Code of 1954.

(4) Amounts received by the Secretary as proceeds from the sale of loans under this subsection shall be deposited in the loan fund established under subsection (e).

(5) Any reference in this title (other than in this subsection and in subsection (d)) to a loan guarantee under

this title does not include a loan guarantee made under this subsection.

(d)(1) There is established in the Treasury a loan guarantee fund (hereinafter in this subsection referred to as the "fund") which shall be available to the Secretary without fiscal year limitation, in such amounts as may be specified from time to time in appropriation Acts, to enable him to discharge his responsibilities under loan guarantees issued by him under this title and to take the action authorized by subsection (f). There are authorized to be appropriated from time to time such amounts as may be necessary to provide the sums required for the fund. To the extent authorized in appropriation Acts, there shall also be deposited in the fund amounts received by the Secretary in connection with loan guarantees under this title and other property or assets derived by him from his operations respecting such loan guarantees, including any money derived from the sale of assets.

(2) If at any time the sums in the funds are insufficient to enable the Secretary to discharge his responsibilities under guarantees issued by him under this title and to take the action authorized by subsection (f), he is authorized to issue to the Secretary of the Treasury notes or other obligations in such forms and denominations, bearing such maturities, and subject to such terms and conditions, as may be prescribed by the Secretary with the approval of the Secretary of the Treasury. Such notes or other obligations shall bear interest at a rate determined by the Secretary of the Treasury, taking into consideration the current average market yield on outstanding marketable obligations of the United States of comparable maturities during the month preceding the issuance of the notes or other obligations. The Secretary of the Treasury shall purchase any notes and other obligations issued under this paragraph and for that purpose he may use as a public debt transaction the proceeds from the sale of any securities issued under the Second Liberty Bond Act, and the purposes for which the securities may be issued under that Act are extended to include any purchase of such notes and obligations. The Secretary of the Treasury may at any time sell any of the notes or other obligations acquired by him under this paragraph. All redemptions, purchases, and sales by the Secretary of the Treasury of such notes or other obligations shall be treated as public debt transactions of the United States. Sums borrowed under this paragraph shall be deposited in the fund and redemption of such notes and obligations shall be made by the Secretary from the fund.

(e) There is established in the Treasury a loan fund (hereinafter in this subsection referred to as the "fund") which shall be available to the Secretary without fiscal year limitation, in such amounts as may be specified from time to time in appropriation Acts, to enable him to make loans under this title and to take the action authorized by subsection (f). There shall also be deposited in the fund amounts received by the Secretary as interest payments and repayment of principal on loans made under this title and other property or assets derived by him from his operations respecting such loans, from the sale of loans under subsection (c) of this section, or from the sale of assets.

(f) The Secretary may take such action as he deems appropriate to protect the interest of the United States in the event of a default on a loan made or guaranteed under this title, including taking possession of, holding, and using real property pledged as security for such a loan or loan guarantee.

### AUTHORIZATIONS OF APPROPRIATIONS

42 U.S.C. 300e-8

Sec. 1309. (a) For the purpose of making payments under grants and contracts under sections 1303, 1304(a), 1304(b), and 1317, there are authorized to be appropriated $25,000,000 for the fiscal year ending June 30, 1974, $55,000,000 for the fiscal year ending June 30, 1975, $40,000,000 for the fiscal year ending June 30, 1976, $45,000,000 for the fiscal year ending September 30, 1977, $45,000,000 for the fiscal year ending September 30, 1978, $31,000,000 for the fiscal year ending September 30, 1979, $65,000,000 for the fiscal year ending September 30, 1980, and $68,000,000 for the fiscal year ending September 30, 1981.

(b) There is authorized to be appropriated to the loan fund established under section 1308(e) $75,000,000 in the aggregate for the fiscal years ending June 30, 1974, and June 30, 1975.

### EMPLOYEES' HEALTH BENEFITS PLANS

42 U.S.C. 300e-9

Sec. 1310. (a)(1) In accordance with regulations which the Secretary shall prescribe—

(A) each employer—

(i) which is now or hereafter required during any calendar quarter to pay its employees the minimum wage prescribed by section 6 of the Fair Labor Standards Act of 1938 (or would be required to pay its employees such wage but for section 13(a) of such Act), and

(ii) which during such calendar quarter employed an average number of employees of not less than 25,

shall include in any health benefits plan, and

(B) any State and each political subdivision thereof which during any calendar quarter employed an average number of employees of not less than 25, as a condition of payment to the State of funds under section 314(d), 317, 318, 1002, 1525, or 1613, shall include in any health benefits plan,

offered to such employees in the calendar year beginning after such calendar quarter the option of membership in qualified health maintenance organizations which are engaged in the provision of basic health services in health maintenance organization service areas in which at least 25 of such employees reside.

(2) If any of the employees of an employer or State or political subdivision thereof described in paragraph (1) are represented by a collective bargining representative or other employee representative designated or selected under any law, offer of membership in a qualified health maintenance organization required by paragraph (1) to be made in a health benefits plan offered to such employees (A) shall first be made to such collective bargaining representative or other employee representative, and (B) if such offer is accepted by such representative, shall then be made to each such employee.

(b) If there is more than one qualified health maintenance organization which is engaged in the provision of basic and supplemental health services in the area in which the employees of an employer subject to subsection (a) reside and if—

(1) one or more of such organizations provides basic health services through physicians or other health professionals who are members of the staff of the organization or a medical group (or groups), and

(2) one or more of such organizations provides basic health services through (A) an individual practice association (or associations), or (B) a combination of such association (or associations), medical group (or groups), staff, and individual physicians and other health professionals under contract with the organization,

then of the qualified health maintenance organizations included in a health benefits plan of such employer pursuant to subsection (a) at least one shall be an organization which provides basic health services as described in clause (1) and at least one shall be an organization which provides basic health services as described in clause (2).

(c) No employer shall be required to pay more for health benefits as a result of the application of this section than would otherwise be required by any prevailing collective bargaining agreement or other legally enforceable contract for the provision of health benefits between the employer and its employees. Each employer which provides payroll deductions as a means of paying employees' contributions for health benefits or which provides a health benefits plan to which an employee contribution is not required and which is required by subsection (a) to offer his employees the option of membership in a qualified health maintenance organization shall, with the consent of an employee who exercises such option, arrange for the employee's contribution for such membership to be paid through payroll deductions.

(d) For purposes of this section, the term "qualified health maintenance organization" means (1) a health maintenance organization which has provided assurances satisfactory to the Secretary that it provides basic and supplemental health services to its members in the manner prescribed by section 1301(b) and that it is organized and operated in the manner prescribed by section 1301(c), and (2) an entity which proposes to become a health maintenance organization and which the Secretary determines will when it becomes operational provide basic and supplemental health services to its members in the manner prescribed by section 1301(b) and will be organized and operated in the manner prescribed by section 1301(c).

(e)(1) Any employer who knowingly does not comply with one or more of the requirements of subsection (a), (b), or (c) shall be subject to a civil penalty of not more than $10,000. If such noncompliance continues, a civil penalty may be assessed and collected under this subsection for each thirty-day period such noncompliance continues. Such penalty may be assessed by the Secretary and collected in a civil action brought by the United States in a United States district court.

(2) In any proceeding by the Secretary to assess a civil penalty under this subsection, no penalty shall be assessed until the employer charged shall have been given notice and an opportunity to present its views on such charge. In determining the amount of the penalty, or the amount agreed upon in compromise, the Secretary shall consider the gravity of the noncompliance and the demonstrated good faith of the employer charged in attempting to achieve rapid compliance after notification by the Secretary of a noncompliance.

(3) In any civil action brought to review the assessment of a civil penalty assessed under this subsection, the court shall, at the request of any party to such action, hold a trial de novo on the assessment of such civil penalty and in any civil action to collect such a civil penalty, the court shall, at the request of any party to such action, hold a trial de novo on the assessment of such civil penalty unless in a prior civil action to review the assessment of such penalty the court held a trial de novo on such assessment.

(f) For purposes of this section, the term "employer" does not include (1) the Government of the United States, the government of the District of Columbia or any territory or possession of the United States, a State or any political subdivision thereof, or any agency or instrumentality (including the United States Postal Service and Postal Rate Commission) of any of the foregoing; or (2) a church, convention or association of churches, or any organization operated, supervised or controlled by a church, convention or association of churches which organization (A) is an organization described in section 501 (c)(3) of the Internal Revenue Code of 1954, and (B) does not discriminate (i) in the employment, compensation, promotion, or termination of employment of any personnel, or (ii) in the extension of staff or other privileges to any physician or other health personnel, because such persons seek to obtain or obtained health care, or participate in providing health care, through a health maintenance organization.

(g) If the Secretary, after reasonable notice and opportunity for hearing to a State, finds that it or any of its political subdivisions has failed to comply with one or more of the requirements of subsection (a), the Secretary shall terminate payments to such State under sections 314(d), 317, 318, 1002, 1525, and 1613 and notify the Governor of such State that further payments under such sections will not be made to the State until the Secretary is satisfied that there will no longer be any such failure to comply.

### RESTRICTIVE STATE LAWS AND PRACTICES

42 U.S.C. 300e-10

SEC. 1311. (a) In the case of any entity—

(1) which cannot do business as a health maintenance organization in a State in which it proposes to furnish basic and supplemental health services because that State by law, regulation, or otherwise—

(A) requires as a condition to doing business in that State that a medical society approve the furnishing of services by the entity,

(B) requires that physicians constitute all or a percentage of its governing body,

(C) requires that all physicians or a percentage of physicians in the locale participate or be permitted to participate in the provision of services for the entity, or

(D) requires that the entity meet requirements for insurers of health care services doing business in that State respecting initial capitalization and establishment of financial reserves against insolvency, and

(2) for which a grant, contract, loan, or loan guarantee was made under this title or which is a qualified health maintenance organization for purposes of section 1310 (relating to employees' health benefits plans),

such requirements shall not apply to that entity so as to prevent it from operating as a health maintenance organization in accordance with section 1301.

(b) No State may establish or enforce any law which prevents a health maintenance organization for which a grant, contract, loan, or loan guarantee was made under this title or which is a qualified health maintenance organization for purposes of section 1310 (relating to employees' health benefits plans), from soliciting members through advertising its services, charges, or other nonprofessional aspects of its operation. This subsection does not authorize any advertising which identifies, refers to, or makes any qualitative judgment concerning, any health professional who provides services for a health maintenance organization.

(c) The Secretary shall, within 6 months after the date of the enactment of this subsection, develop a digest of State laws, regulations, and practices pertaining to development, establishment, and operation of health maintenance organizations which shall be updated at least quarterly and relevant sections of which shall be provided to the Governor of each State annually. Such digest shall indicate which State laws, regulations, and practices appear to be inconsistent with the operation of this section. The Secretary shall also insure that appropriate legal consultative assistance is available to the States for the purpose of complying with the provisions of this section.

### CONTINUED REGULATION OF HEALTH MAINTENANCE ORGANIZATIONS

SEC. 1312. (a) If the Secretary determines that an entity which received a grant, contract, loan, or loan guarantee under this title as a health maintenance organization or which was included in a health benefits plan offered to employees pursuant to section 1310— 42 U.S.C. 300e–11

(1) fails to provide basic and supplemental services to its members,

(2) fails to provide such services in the manner prescribed by section 1301(b), or

(3) is not organized or operated in the manner prescribed by section 1301(c),

the Secretary may take the action authorized by subsection (b).

(b)(1) If the Secretary makes, with respect to any entity which provided assurances to the Secretary under section 1310(d)(1), a determination described in subsection (a), the Secretary shall notify the entity in writing of the determination. Such notice shall specify the manner in which the entity has not complied with such assurances and direct that the entity initiate (within 30 days of the date the notice is issued by the Secretary or within such longer period as the Secretary determines is reasonable) such action as may be necessary to bring (within such period as the Secretary shall prescribe) the entity into compliance with the assurances. If the entity fails to initiate corrective action within the period prescribed by the notice or fails to comply with the assurances within such period as the Secretary prescribes (A) the entity shall not be a qualified health maintenance organization for purposes of section 1310 until such date as the Secretary determines that it is in compliance with the assurances, and (B) each employer which has offered membership in the entity in compliance with section 1310, each lawfully recognized collective bargaining representative or other employee representative which represents the employees of each such employer, and the members of such entity shall be notified by the entity that the entity is not a qualified health maintenance organization for purposes of such section. The notice required by clause (B) of the preceding sentence shall contain, in readily understandable language, the reasons for the determination that the entity is not a qualified health maintenance organization. The Secretary shall publish in the Federal Register each determination referred to in this paragraph.

(2) If the Secretary makes, with respect to an entity which has received a grant, contract, loan, or loan guarantee under this title, a determination described in subsection (a), the Secretary may, in addition to any other remedies available to him, bring a civil action in the United States district court for the district in which such entity is located to enforce its compliance with the assurances it furnished respecting the provision of basic and supplemental health services or its organization or operation, as the case may be, which assurances were made in connection with its application under this title for the grant, contract, loan, or loan guarantee.

### LIMITATION ON SOURCE OF FUNDING FOR HEALTH MAINTENANCE ORGANIZATIONS

42 U.S.C. 300e-12

SEC. 1313. No funds appropriated under any provision of this Act (except as provided in sections 329, 330, and 340) other than this title may be used—

(1) for grants or contracts for surveys or other activities to determine the feasibility of developing or expanding health maintenance organizations or other entities which provide, directly or indirectly, health services to a defined population on a prepaid basis;

(2) for grants or contracts, or for payments under loan guarantees, for planning projects for the establishment or expansion of such organizations or entities;

(3) for grants or contracts, or for payments under loan guarantees, for projects for the initial development or expansion of such organizations or entities; or

(4) for loans, or for payments under loan guarantees, to assist in meeting the costs of the initial operation after establishment or expansion of such organizations or entities or in meeting the costs of such organizations in acquiring or constructing ambulatory health care facilities.

### PROGRAM EVALUATION

SEC. 1314. (a) The Comptroller General shall evaluate the operations of at least ten or one-half (whichever is greater) of the health maintenance organizations for which assistance was provided under sections 1303, 1304, and 1305, and which, by December 31, 1976, have been designated by the Secretary under section 1310(d) as qualified health maintenance organizations. The Comptroller General shall report to the Congress the results of the evaluation by June 30, 1978. Such report shall contain findings— 42 U.S.C. 300e–13

(1) with respect to the ability of the organizations evaluated to operate on a fiscally sound basis without continued Federal financial assistance,

(2) with respect to the ability of such organizations to meet the requirements of section 1301(c) respecting their organization and operation,

(3) with respect to the ability of such organizations to provide basic and supplemental health services in the manner prescribed by section 1301(b),

(4) with respect to the ability of such organizations to include indigent and high-risk individuals in their membership, and

(5) with respect to the ability of such organizations to provide services to medically underserved populations.

(b) The Comptroller General shall also conduct a study of the economic effects on employers resulting from their compliance with the requirements of section 1310. The Comptroller General shall report to the Congress the results of such study not later than thirty-six months after the date of the enactment of this title.

(c) The Comptroller General shall evaluate (1) the operations of distinct categories of health maintenance organizations in comparison with each other, (2) health maintenance organizations as a group in comparison with alternative forms of health care delivery, and (3) the impact that health maintenance organizations, individually, by category, and as a group, have on the health of the public. The Comptroller General shall report to the Congress the results of such evaluation not later than thirty-six months after the date of the enactment of this title.

(d) The Comptroller General shall evaluate the adequacy and effectiveness of the policies and procedures of the Secretary for the management of the grant and loan programs established by this title and the adequacy of the amounts of assistance available under such programs and shall report to the Congress the results of such evaluation not later than May 1, 1979.

### ANNUAL REPORT

42 U.S.C. 300e-14

SEC. 1315. (a) The Secretary shall periodically review the programs of assistance authorized by this title and make an annual report to the Congress of a summary of the activities under each program. The Secretary shall include in such summary—

(1) a summary of each grant, contract, loan, or loan guarantee made under this title in the period covered by the report and a list of the health maintenance organizations which during such period became qualified health maintenance organizations for purposes of section 1310;

(2) the statistics and other information reported in such period to the Secretary in accordance with section 1301(c)(11);

(3) findings with respect to the ability of the health maintenance organizations assisted under this title—

(A) to operate on a fiscally sound basis without continued Federal financial assistance,

(B) to meet the requirements of section 1301(c) respecting their organization and operation,

(C) to provide basic and supplemental health services in the manner prescribed by section 1301(b),

(D) to include indigent and high-risk individuals in their membership, and

(E) to provide services to medically underserved populations; and

(4) findings with respect to—

(A) the operation of distinct categories of health maintenance organizations in comparison with each other,

(B) health maintenance organizations as a group in comparison with alternative forms of health care delivery, and

(C) the impact that health maintenance organizations, individually, by category, and as a group, have on the health of the public.

(b) The Office of Management and Budget may review the Secretary's report under subsection (a) before its submission to the Congress, but the Office may not revise the report or delay its submission, and it may submit to the Congress its comments (and those of other departments or agencies of the Government) respecting such report.

## ADMINISTRATION OF PROGRAM

42 U.S.C. 300e-15

SEC. 1316. The Secretary shall administer this title (other than sections 1310 and 1312) through a single identifiable administrative unit of the Department.

## TRAINING AND TECHNICAL ASSISTANCE

42 U.S.C. 300e-16.

SEC. 1317. (a)(1) The Secretary shall establish a National Health Maintenance Organization Intern Program (hereinafter in this subsection referred to as the "Program") for the purpose of providing training to individuals to become administrators and medical directors of health maintenance organizations or to assume other managerial positions with health maintenance organizations. Under the Program the Secretary may directly provide internships for such training and may make grants to or enter into contracts with health maintenance organizations and other entities to provide such internships.

(2) No internship may be provided by the Secretary and no grant may be made or contract entered into by the Secretary for the provision of internships unless an application therefor has been submitted to and approved by the Secretary. Such an application shall be in such form and contain such information, and be submitted to the Secretary in such manner, as the Secretary shall prescribe. Section 1306 does not apply to an application submitted under this section.

(3) Internships under the Program shall provide for such stipends and allowances (including travel and subsistence expenses and dependency allowances) for the recipients of the internships as the Secretary deems necessary. An internship provided an individual for training at a health maintenance organization or any other entity shall also provide for payments to be made to the organization or other entity for the cost of support services (including the cost of salaries, supplies, equipment, and related items) provided such individual by such organization or other entity. The amount of any such payments to any organization or other entity shall be determined by the Secretary and shall bear a direct relationship to the reasonable costs of the organization or other entity for establishing and maintaining its training programs.

(4) Payments under grants under the Program may be made in advance or by way of reimbursement, and at such intervals and on such conditions, as the Secretary finds necessary.

(b) The Secretary shall provide technical assistance (1) to entities in connection with projects for which assistance is being provided under section 1303 or 1304, (2) to entities intending to become a qualified health maintenance organization within the meaning of section 1310 (d), and (3) to health maintenance organizations. The

Secretary may provide such technical assistance through grants to public and nonprofit private entities and contracts with public and private entities.

(c) The authority of the Secretary to enter into contracts under subsections (a) and (b) shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance by appropriation Acts.

### FINANCIAL DISCLOSURE

42 U.S.C. 300e–17

SEC. 1318. (a) Each health maintenance organization shall, in accordance with regulations of the Secretary, report to the Secretary financial information which shall include the following:

(1) Such information as the Secretary may require demonstrating that the health maintenance organization has a fiscally sound operation.

(2) The information required to be reported under section 1124 of the Social Security Act by disclosing entities and the information required to be supplied under section 1902(a)(38) of such Act.

(3) A description of transactions, as specified by the Secretary, between the health maintenance organization and a party in interest. Such transactions shall include—

(A) any sale or exchange, or leasing of any property between the health maintenance organization and a party in interest;

(B) any furnishing for consideration of goods, services (including management services, but excluding health services provided to members by staff, medical group (or groups), individual practice association (or associations), or any combination thereof), or facilities between the health maintenance organization and a party in interest; and

(C) any lending of money or other extension of credit between a health maintenance organization and a party in interest.

The Secretary may require that information reported respecting a health maintenance organization which controls, is controlled by, or is under common control with, another entity be in the form of a consolidated financial statement for the organization and such entity.

(b) For the purposes of this section the term "party in interest" means:

(1) any director, officer, partner, or employee of a health maintenance organization, any person who is directly or indirectly the beneficial owner of more than 5 per centum of the equity of the organization, any person who is the beneficial owner of a mortgage, deed of trust, note, or other interest secured by, and valuing more than 5 per centum of the health main-

tenance organization, and, in the case of a health maintenance organization organized as a nonprofit corporation, an incorporator or member of such corporation under applicable State corporation law;

(2) any entity in which a person described in paragraph (1)—

(A) is an officer or director;

(B) is a partner (if such entity is organized as a partnership);

(C) has directly or indirectly a beneficial interest of more than 5 per centum of the equity; or

(D) has a mortgage, deed of trust, note, on other interest valuing more than 5 per centum of the assets of such entity;

(3) any person directly or indirectly controlling, controlled by, or under common control with a health maintenance organization; and

(4) any member of the immediate family of an individual described in paragraph (1).

(c) Each health maintenance organization shall make the information reported pursuant to subsection (a) available to its enrollees upon reasonable request.

(d) The Secretary shall, as he deems necessary, conduct an evaluation of transactions reported to the Secretary under subsection (a)(3) for the purpose of determining their adverse impact, if any, on the fiscal soundness and reasonableness of charges to the health maintenance organization with respect to which they transpired. The Secretary shall evaluate the reported transactions of not less than five, or if there are more than twenty health maintenance organizations reporting such transactions, not less than one-fourth of the health maintenance organizations reporting any such transactions under subsection (a)(3).

(e) The Secretary shall file an annual report with the Congress on the operation of this section. Such report shall include—

(1) an enumeration of standards and norms utilized to make the evaluations required under subsection (d);

(2) an assessment of the degree of conformity or nonconformity of each health maintenance organization evaluated by the Secretary under subsection (d) with such standards and norms;

(3) what action, if any, the Secretary considers necessary under section 1312 with respect to health maintenance organizations evaluated under subsection (d).

(f) Nothing in this section shall be construed to confer upon the Secretary any authority to approve or disapprove the rates charged by any health maintenance organization.

(g) Any health maintenance organization failing to file with the Secretary the annual financial statement required in subsection (a) shall be ineligible for any Federal assistance under this title until such time as such statement is received by the Secretary and shall not be a qualified health maintenance organization for purposes of section 1310.

(h) Whoever knowingly and willfully makes or causes to be made any false statement or representation of a material fact in any statement filed pursuant to this section shall be guilty of a felony and upon conviction thereof shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

# SECTION III

## Current and Proposed Regulations
## Governing Title XIII

## Title XIII

## Final and Interim Regulations Update[1/]

| Subpart | Publication Date | Effective Date | Instructions to Update Regulations |
|---|---|---|---|
| A (Final - attached) | 10/31/80 | 12/1/80 | Replace this subpart. |
| B (Final - amended, attached) | 8/18/80 | 8/18/80 | Merge with 42 CFR 110 dated 10/1/79. |
| C - (Final) | 10/27/78 | 10/27/78 | No change. |
| D & E (Final - amended) | 1/24/80 | 1/24/80 | No change. |
| F (Interim) | 6/8/77 | 6/8/77 | No change |
| G (Final) | 10/18/74 | 10/18/74 | No change |
| H (Final - attached) | 10/31/80 | 12/1/80 | Replace this subpart. |
| I (Final) | 7/25/78 | 8/24/78 | No change. |
| J (Interim) | 4/9/80 | 4/9/80 | No change. |

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1/ Refer to regulations' section in OHMO Policy Manual

## Notice of Proposed Rulemaking

| | |
|---|---|
| Reporting & Disclosure Requirements Under "ERISA" | 6/22/79 |

November 21, 1980

Revised as of 10/1/79

# SUBCHAPTER J—HEALTH CARE DELIVERY SYSTEMS

## PART 110—HEALTH MAINTENANCE ORGANIZATIONS

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## Subpart J—Fair Hearing [Reserved]

AUTHORITY: Sec. 215, 58 Stat. 690, (42 U.S.C. 216); secs. 1301-1316, as amended, 90 Stat. 1945-1960 (42 U.S.C. 300e-300e-15), unless otherwise noted.

SOURCE: 40 FR 37311, Oct. 18, 1974, unless otherwise noted.

## Office of Health Maintenance Organizations

Policy Manual

Errata Sheet

### Subpart A

§ 110.104(b) - The word "four" was omitted in the first sentence. It should read: "(b) After the expiration of the first four fiscal years of an HMO . . . "

§ 110.108(c) - In the first sentence delete next to the last word "device" and substitute the word service. The sentence should read: "After full and fair disclosure of its benefits, coverage, rates, grievance procedures, location, and hours of service, and a general description of its participating providers and financial condition, each HMO shall offer enrollment to persons who are broadly representative of the various age, social, and income groups within its service area. . . . "

### Subpart H

§ 110.806(d)(2) - Under Illustrative Examples: 1. Note: In the last sentence delete next to the last word "non-HMO" and substitute the word HMO. The sentence should read: " . . . Conversely, if this coverage is optional for employees selecting the non-HMO option, nothing in this regulation requires that the coverage be mandatory for employees selecting the HMO option."

November 1, 1980

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**42 CFR Part 110**

## Health Maintenance Organizations; Requirements for a Health Maintenance Organization

**AGENCY:** Public Health Service, HHS.

**ACTION:** Final regulations.

**SUMMARY:** This rule amends the Public Health Service regulations by setting forth revised requirements for the organization and operation of federally qualified health maintenance organizations (HMOs). These amendments are made as a result of (1) public comments on the interim regulations published on July 18, 1979, and (2) public comments on the notice of proposed rulemaking (NPRM) governing relationships between federally qualified HMOs and other parties, also published on July 18, 1979.

**EFFECTIVE DATE:** This rule is effective on December 1, 1980.

**FOR FURTHER INFORMATION CONTACT:** Howard R. Veit, Director, Office of Health Maintenance Organizations, Park Building, 3rd Floor, 12420 Parklawn Drive, Rockville, Maryland 20857, 301/443-4106.

**SUPPLEMENTARY INFORMATION:** On July 18, 1979, interim regulations were published in the **Federal Register** (44 FR 42060–71) to amend 42 CFR Part 110, Subpart A, issued under Title XIII of the Public Health Service Act (the Act). Interested persons were given an opportunity to submit comments concerning these regulations by September 17, 1979. Fifteen persons submitted comments on the interim final regulations. Also on July 18, 1979, an NPRM was published in the **Federal Register** (44 FR 41838–41) concerning the relationships between federally qualified HMOs and other parties. The Secretary invited comments by September 17, 1979, and stated that after the public comments were received, the policies would be revised as warranted and incorporated into regulations or set forth as interpretive rulings, as appropriate. Ten persons submitted comments on the NPRM.

The following are summarized below: (1) The comments received, responses thereto, and the changes made, if any, on the Subpart A interim final regulations; (2) the comments received, responses thereto, and the changes made, if any, in the policies stated in the NPRM on relationships between federally qualified HMOs and other parties, including which of these policies have been added, and where, to the Subpart A regulations; and (3) the changes made to correct technical problems in the regulations.

The Department also notes that on April 29, 1980, at 45 FR 28654–63, it published in the **Federal Register** a series of informational questions and answers based on the interim regulations for Subpart A. The Department refers the public to that document for further information on the requirements of Subpart A. It notes that the document will be amended as appropriate in the near future to reflect the revisions made to the Subpart A regulations by this notice.

### Subpart A Interim Final Regulations

1. Section 110.102 addresses the required health benefits for basic health services, including short-term rehabilitation and physical therapy. Several commenters requested clarification of the duration of these "short-term" services. The regulations have been changed to specify that short-term rehabilitation services and physical therapy must be provided if the HMO determines that the provision of these services can be expected to result in significant improvement of a member's condition within a period of two months. The physical therapy requirement has been moved from § 110.102(a)(2)(ii) to § 110.102(a)(2)(iii) to clarify that short-term physical therapy is required on both an outpatient and inpatient basis.

2. Section 110.102(a)(5)(ii), pertaining to referral services for the abuse of or addiction to alcohol and drugs, has been amended to indicate that prolonged rehabilitation services for alcohol or drug abuse or addiction in a specialized inpatient or residential facility need not be offered by an HMO as a basic health service. The Department notes, however, that an HMO may choose to offer prolonged rehabilitation services as a supplemental health service. This change is in response to a request by a commenter that this information, which was included in the preamble of the interim regulations, be incorporated into the final regulations.

3. Section 110.102(d) lists the permissible exclusions from the required basic health services. Section 110.102(d)(9) has been modified at the request of a commenter who noted that the exclusion of vision and hearing care as a basic health service failed to take into consideration that some vision and hearing services may be a part of physician services, such as care for diseases of the eye and ear, as well as preventive health services, as in the case of eye and ear examinations for children through age 17 to determine the need for vision or hearing correction. The exclusion for vision and hearing care has been clarified to indicate that this care need not be provided as a basic health service except as required by sections 1302(1)(A) and 1302(1)(H)(vi) of the Act and §§ 110.102(a)(1) and 110.102(a)(8) of these regulations.

4. Section 110.104(a)(2), pertaining to non-conforming medical groups, has been changed and is now § 110.104(a)(3). This revised section clarifies that after the four-year period which follows the month in which the HMO was qualified, the HMO may provide services through a non-conforming medical group if it meets the definition of medical group as set forth in § 110.101 or if the Secretary has determined that the entity meets the conditions set forth in § 110.104(a)(3)(ii). A suggestion to permit the four-year period allowed for the use of a non-conforming medical group to commence from the date of the HMO's contract with the group has been rejected because section 1301(b)(3)(B)(ii) of the Act indicates that the four-year period is to be calculated from the month after the HMO's qualification date.

5. One commenter requested clarification of the requirements that apply to the HMO's contracts for health services under § 110.104(c). In response, the Department has separated this paragraph into two subparagraphs to delineate clearly the difference between the requirements for (1) contracts between the HMO and medical groups or IPAs, and (2) direct service contracts between the HMO and health professionals. Section 110.104(c)(1) now lists the requirements for the former type of contract and § 110.104(c)(2) clarifies that the contract between the HMO and its health professionals must include provisions for appropriate continuing education in addition to four of the provisions which an HMO must include in its contracts with medical groups or IPAs: a description of the responsibilities of the parties to the contract; the agreed upon compensation for services; an agreement that the contracting parties will look solely to the HMO for compensation for services provided to HMO members; and a provision specifically requiring participation by health professionals in the quality assurance activities which the HMO is required to have under § 110.108(j).

6. Section 110.105(e) states that HMOs may charge a late payment penalty on accounts receivable which are in arrears. The Department has not adopted the suggestion that the regulations require 30 days written notice or limit the HMO's late payment

penalty charges to amounts which are not in dispute. These limitations are not properly within the scope of the Act. Of course, an HMO may agree to these limitations.

7. Section 110.108(a)(1) requires an HMO to have a fiscally sound operation. In the preamble to the interim final regulations, the Secretary expressed the intention of using a ratio of current assets to current liabilities of at least one-to-one as a benchmark in administering the cash flow requirement of § 110.108(a)(1)(ii). A commenter noted that current liabilities may exceed current assets at any given date, because the former may include a significant amount of prepaid dues (deferred income) and the latter a relatively low amount for receivables. Further, the proposed ratio test was cited as an inappropriate benchmark for evaluating adequacy of cash flow because cash flow is dynamic and the ratio test is a static measure of liquidity. The Department agrees with these comments and notes that the adequacy of cash flow will now be examined on a case-by-case basis to assure that the HMO can meet its obligations as they become due. Accordingly, the requirement at § 110.108(a)(1)(ii) has been changed to require an HMO to provide evidence of its ability to meet its obligations as they become due, as determined by sufficient cash flow and by adequate liquidity. The evaluation of the maintenance of adequate liquidity will start with the ratio test of current assets to current liabilities of at least one-to-one, but will allow for valid deviations such as the situation noted in this paragraph.

8. The Department received a number of inquiries as to the scope of § 110.108(a)(2)(i), which sets out the standards for the satisfactory administrative and managerial arrangements with respect to the HMO's policymaking body. In particular, the inquiries have focused on the requirement that the policymaking body "*exercises oversight and control* over the HMO's policy and personnel to assure that management actions are in the best interest of the HMO and its membership" (Emphasis added). In order to determine whether the HMO's policymaking body has the capability to and does in fact carry out these responsibilities and thus meets the requirements of § 110.108(a)(2)(i), the Department requires the HMO to demonstrate that its policymaking body has the appropriate skills (e.g., planning, financial management and evaluation skills) to perform these oversight and control functions.

9. The Department has received a number of questions as to whether it is permissible for federally qualified HMOs to expel or refuse to reenroll their members who have reached age 65. The Department's position has always been that the expulsion of such persons by an HMO is inconsistent with Title XIII of the Act. (The expulsion of the aged by HMOs receiving Federal financial assistance may also violate the Age Discrimination Act of 1975, as amended. (42 U.S.C. 6101 *et seq.*)) In order to avoid confusion in this regard, the Department has decided to incorporate this prohibition expressly into the regulations. Accordingly, § 110.108(f), which prohibits an HMO from expelling or refusing to reenroll any member, as well as from refusing to enroll individual members of a group, on the basis of the health status or health care needs of the member or individual, has been modified by adding age as an impermissible basis for such actions by the HMO. It is still permissible, of course, for HMOs to require that, as a condition of continued eligibility for membership, dependents of a subscriber, upon reaching a specified age, convert to nongroup membership in accordance with § 110.108(g).

10. Section 110.108(g) had required an HMO to offer conversion privileges to subscribers leaving a group "on the same terms and conditions as are available to a nongroup subscriber." Because this requirement was phrased in terms of "subscribers," a number of commenters expressed confusion as to the conversion privileges which the HMO is required to offer "members" who would otherwise lose their eligibility for HMO membership. Since the language was inadvertently narrower than intended, the regulation has been changed to require an HMO to offer membership on the same terms and conditions as are available to a nongroup subscriber to:

(1) Each subscriber (and enrolled dependents) leaving a group; and

(2) Each member who would otherwise cease to be eligible for HMO membership because of his or her age or the death or divorce of a subscriber.

11. Section 110.108(k) pertains to certification of providers. The Department agrees with a comment that it is not necessary to require non-institutional providers to be certified by Medicare or Medicaid. It notes that the requirements of this section are intended to insure that HMO institutional providers are certified in accordance with Federal or national certification standards. Since individual providers are required to meet State licensure requirements, and since certification of certain health professionals under Title XVIII or Title XIX of the Social Security Act is for reimbursement purposes only, the requirements have been changed to require that the HMO offer institutional services only through institutional providers that maintain such certification. Hospitals, however, may satisfy the "certification" requirement either by certification under Title XVIII or by accreditation by the Joint Commission on Accreditation of Hospitals. The requirements as to clinical laboratories through which the HMO provides services (except for laboratories exempted from section 353 of the Public Health Service Act, "Licensing of Laboratories," by paragraphs (d)(2), (i) or (1) of that section), must either be certified under Medicare or Medicaid or be licensed under section 353. The Department notes that these regulations do not apply to the HMO's own laboratory, although the laboratory may otherwise be subject to the requirements of section 353 or Medicare or Medicaid.

12. Section 110.108(o) covers reporting and disclosure requirements for HMOs and § 110.108(o)(1) requires HMOs to furnish specific reports to the general public upon request. One commenter inquired where a request by the public for information which an HMO has reported to the Department under § 110.108(o)(1) should be directed. The Department notes that requests regarding information reported under this subsection may be directed to the HMO, in accordance with the HMO's reporting procedure, or to the Department's Office of Health Maintenance Organizations.

13. A number of commenters noted that § 110.108(o)(2)(ii), which sets out which transactions between an HMO and a party in interest must be disclosed to the Secretary, imposed a heavy reporting burden on HMOs. Accordingly, the section has been changed. It would require the reporting only of *significant* business transactions between the HMO and a party in interest, instead of the previous requirement that *all* such business transactions be reported. The term "significant business transaction" is adapted from the Department's Medicare-Medicaid regulations at 42 CFR 420.201, which govern the disclosure of ownership and control information by providers, intermediaries, and carriers. For purposes of § 110.108(o)(2)(ii), the term is defined (see § 110.101) as "any business transaction or series of transactions during any one fiscal year

of the HMO, the total value of which exceeds the lesser of $25,000 or five percent of the total operating expenses of the HMO."

14. Section 110.108(o)(2)(ii)(B) requires an HMO to disclose, among other items, certain transactions between itself and a party in interest for the furnishing of services. A commenter suggested that since the ordinary employee-employer relationship does not constitute a suspect or potentially abusive transaction, services provided by employees of the HMO in the normal course of their employment should be excluded from services which are subject to disclosure. The Secretary agrees with this comment and has changed § 110.108(o)(2)(ii)(B) to exclude transactions for these services from those subject to disclosure.

### NPRM on Relationships Between Federally Qualified HMOs and Other Parties

The NPRM addressed issues that arose under five general headings: (1) The legal structure of an HMO, (2) the HMO's conduct of other activities, (3) the activities of providers affiliated with the HMO, (4) arrangements for HMO contract services, and (5) maximizing HMO enrollment. The Secretary has decided to finalize the policies which were detailed in the NPRM as follows: (1) Certain of the policies set forth in the NPRM, as clarified in response to comments, are now incorporated into the subpart A regulations, as detailed in the first section below, and (2) the remainder of the policies set forth in the NPRM, as clarified in response to comments, are summarized in the second section below. These latter policies have been adopted as official policies of the Department and are set forth in the informational document referred to above (45 FR 28654–63).

### Third Party Policies Incorporated Into the Subpart A Regulations

1. Section 110.104(a) addresses the requirements for providers of basic and supplemental health services. A new § 110.104(a)(2) has been added, which modifies the policy set forth in the NPRM that would have permitted sharing of physicians by alternative model HMOs, but only to the extent that the physicians the IPA shares with the alternative model HMO (i.e., either a staff or medical group model) constituted less than 50 percent of the physicians participating in the IPA. Two commenters, citing a lack of statutory authority, objected to this requirement and questioned the basis for the 50 percent limitation. The Department notes that the purpose behind the enactment of section 1310(b), which requires employers in certain circumstances to offer their employees the option of membership in different model HMOs, is to encourage competition among different model HMOs (as well as between HMOs (as well as between HMOs and other health care providers) by providing employees with real "alternatives from which to choose for their care." (H.R. Rep. #93-451, 93rd Cong., 1st Sess. p. 39). If alternative model HMOs were to offer services to HMO members through the same physicians, the result would defeat the essential purpose of section 1310(b) by limiting genuine consumer choice. Accordingly, the Department believes a limitation is necessary to assure that the purpose of section 1310(b) is fulfilled. However, it agrees that a 50 percent limitation, in the absence of other information, may not be appropriate. Therefore, the regulation at § 110.104(a)(2) permits physician sharing between an IPA and medical group or staff HMO of 50 percent or more, but only if this sharing is approved by the Secretary as being consistent with the purposes of section 1310(b). The Secretary will, on a case-by-case basis, review the characteristics of those HMOs which share physicians in excess of the 50 percent limitation, taking into account the following factors: (1) The total number of practicing physicians in the service area of each HMO which proposes to share physicians with another HMO, (2) the number of physicians to be shared as a percentage of the IPA's total pool, (3) the specialties of the shared physicians, (4) the overlap of the service areas of the HMOs which propose sharing, (5) the practice location of the shared physicians in relation to the location of the other HMO physician providers, and (6) such other factors as the Secretary may consider necessary in determining whether the sharing of physicians enables the HMOs to meet the purpose of section 1310(b).

The Department notes that there is no limitation of physician sharing by competing IPAs or by competing IPA model HMOs, since the purpose of encouraging different model HMOs to compete with each other is not applicable in these situations. All HMOs must, of course, assure the accessibility and availability of services to their members.

2. Section 110.108(a)(1), which requires the HMO to have a fiscally sound operation, has been expanded to incorporate the policy set out in the NPRM that all HMOs shall maximize their enrollment.

Although the NPRM invited the public to suggest standards to determine whether on HMO is maximizing its enrollment, none of the four comments received suggested any such standards. For example, one commenter, noting that flexible indicators were preferable to standards, suggested that the Department meet with representatives of the HMO industry to develop such indicators. Another commenter suggested standards for determining whether an HMO has failed, as opposed to succeeded, in maximizing its enrollment. Noting that none of the comments received suggested for determining whether an HMO is maximizing its enrollment, the Department has determined that it is not feasible to set such uniformly applicable standards. Rather, is has decided that it is more appropriate to implement this policy by requiring (at § 110.108(a)(1)(vii)), that each HMO submit a plan to maximize its enrollment. The Department notes that it will only examine the extent to which the HMO has maximized its enrollment as it relates to the HMO's continued fiscal soundness.

The Department also notes that while membership growth is essential to the development and maintenance of a financially viable HMO, HMOs must monitor their growth in the context of per member per month revenues and costs. Accordingly, the HMO's efforts to maximize enrollment must be consistent with sound management.

3. Section 110.108(h)(1) sets forth the requirement that at least one-third of the HMO's policymaking body must be members of the HMO. This section has been modified to incorporate the policy set forth in the NPRM that the one-third of the policymaking body who are members of the HMO must reside in or in proximity to the HMO's service area. This policy is based on the clear Congressional intent to require member participation in the HMO policymaking body in order to assure that input is available from individuals who represent the viewpoint of users of the HMO's services.

The Department received a request to clarify this requirement with respect to (1) an HMO with regional components and one overall policy body, and (2) different HMOs with policymaking bodies consisting of the same members. The regulation now specifies that the one-third member portion of the policymaking body shall consist of individuals who live in or in proximity to the service area of at least one regional component of the HMO or at least one of the HMOs, respectively.

4. The NPRM reiterated the policy that an HMO may not offer prepaid health benefits which do not meet the requirements of the Act. This prohibition is already included in the regulations, at § 110.102(e), which prohibits an HMO from offering to provide or arrange for the provision of prepaid basic health services which do not meet the requirements of § 110.102(a).

5. A new § 110.109, *Prohibited Activities*, has been added. This section prohibits an HMO, including its employees in the normal course of their employment, from selling, marketing, or promoting, directly or through arrangements with other entities, health insurance or health service benefit plans for health benefits which are included in the health benefits package offered by the HMO to an individual or a group. Thus, for any individual or group, the HMO may not sell, market, or promote health insurance or a health service benefit plan for a benefit for which the member is eligible to receive services under his or her prepaid benefit package. In the NPRM, the Department had proposed to prohibit the "promotion or sale" by an HMO of "competing health insurance." Two commenters, noting that this prohibition could be evaded by the sale of competing health insurance through the marketing staff of an HMO who are licensed as individuals, suggested that the prohibition be extended to selling, promoting, or marketing through the HMO's employees or through other arrangements (such as by an arrangement with another entity). Another commenter noted that the phrase "competing health insurance" was vague and imprecise. Since the Department agrees with these comments, it has structured the prohibition to (1) apply to an HMO and to its employees, (2) encompass marketing as well as selling or promoting, and (3) apply to health insurance and health service benefit plans, instead of competing health insurance. However, the Department has limited the prohibition, as to any individual or group, to benefits which the HMO includes in the prepaid health benefit package offered to that individual or group. Thus, for example, if an HMO does not include dental services in the prepaid benefit package it offers to an individual, it would not be prohibited from offering that individual coverage for dental services through an indemnity insurance or health service benefit plan.

Five commenters opposed the proposed restrictions on an HMO's activities. These commenters suggested that the Secretary did not have the statutory authority to limit the HMO's activities. They also characterized the proposed policy as anti-competitive and as detrimental to HMOs, on the basis that an HMO would be prohibited from engaging in certain activities while similar restrictions were not placed on its competitors. The Department believes that the restriction is consistent with the statute. The Department notes that the purpose of Congress in enacting Title XIII of the Act was to foster competition by making HMOs available as a genuine alternative health delivery system, rather than to foster entities which sell, promote or market health insurance or health service benefits plans which compete with the HMO's benefit package. (See S. Rep. No. 93–129, 93rd Cong., 1st Sess. pp. 7, 8 (1973) and H.R. Rep. No. 93–451, 93rd Cong., 1st Sess. p. 8 (1973).) The Department notes that permitting an HMO or its employees to engage in the activities prohibited by § 110.109 would defeat the purpose of Title XIII because it would reduce the incentives for the HMO to offer its qualified prepaid health benefits package in a competitive manner, which might then threaten the fiscal soundness of the HMO. Accordingly, the Department views this limited prohibition as being within the scope of its authority under Title XIII and necessary for its proper implementation.

As to the comments suggesting that the proposed restriction was anti-competitive, the Department believes that the limitation which it has added to § 110.109 has addressed these concerns. Because the HMO is not prohibited from offering indemnity insurance or health service benefit plan coverage for services it does not include in its prepaid health benefit plan, it would be free to respond to a competitive situation by doing so. The HMO would, of course, have the alternative option of offering the services at issue on a prepaid basis as part of its prepaid health benefit package. In the Department's view, this array of options available to the HMO enhances the HMO's competitive posture.

The former §§ 110.109 and 110.110 have been renumbered as §§ 110.110 and 110.111, respectively.

One commenter inquired whether it is permissible for an HMO to own or control a subsidiary that is a separate legal entity and, if so, whether there are any prohibitions on the activities of an HMO's subsidiaries. Nothing in the Act prohibits an HMO from having a subsidiary that is a separate legal entity. Furthermore, at this time there are no prohibitions on the activities of an HMO's subsidiaries. For example, the prohibition at § 110.109 applies to the HMO entity only; it does not apply to subsidiaries of HMOs.

The Department is, however, currently collecting data on the activities of HMO subsidiaries. In particular, the Department is evaluating whether HMO subsidiaries are (1) offering to provide or arrange for prepaid services which do not meet the requirements of Title XIII, or (2) selling, marketing, or promoting, directly or through arrangements with other entities, health insurance or health service benefit plans in the manner prohibited (as to the HMO itself) by the new § 110.109. The Department intends to analyze these data to determine what prohibitions, if any, should be applicable to the activities of HMO subsidiaries. If it appears that some prohibitions might be appropriate, the Department will issue a notice of proposed rulemaking setting forth its proposed policies, invite public comments, and finalize the policies and incorporate them into regulations or set them forth as interpretive rulings, as appropriate.

### Other Third Party Policies

1. As set forth in the NPRM, an HMO is required to be a separate legal entity; it may not be a cost center or separate line of business of a sponsor organization. However, an HMO may be a subsidiary of another legal entity as long as the HMO is itself a legal entity with its own policymaking body.

Three commenters, concerned about the requirement noted in the NPRM that each HMO must b a separate legal entity, suggested an exemption from this requirement for public HMOs. Section 1301(a) of the Act and § 110.101 of these regulations, which include in the definition of an HMO the requirement that it be a legal entity, do not distinguish between public and private HMOs. However, the Secretary notes that a public HMO may be administered by a cost center or a department of a public entity, as long as the HMO is the legal entity.

2. The policy that officers, directors, and employees of a sponsoring organization may be included in the non-member portion of the HMO's policymaking body remains as described in the NPRM.

3. The policy that the Department does not intend to regulate the scope of the activities in which a medical group may engage when it is not providing services to members of its affiliated HMO remains as stated in the NPRM. In response to a comment, the Secretary notes that this policy applies to the non-

HMO activities of an individual practice association as well.

4. The policies as to the extent to which HMOs may contract with other parties to perform certain administrative functions which the HMO elects not to perform itself remains as stated in the NPRM. (See 44 FR 41840, section 4).

### Technical Changes

1. Section § 110.104(b) has been changed to clarify that payments made by an HMO for physician services from a non conforming medical group that meets the requirements set forth in § 110.104(a)(3)(ii) will not be counted against the 15 percent limitation on contracting which applies to an HMO four years following the month after its qualification.

2. Section § 110.104(c)(1)(vi) (formerly § 110.104(c)(4)) has been corrected to indicate that the requirement for professional liability coverage applies to medical groups and IPAs *or* the health professionals associated with them, rather than to medical groups, IPAs *and* health professionals associated with them. The interim final regulations contained the correct language in the preamble; however, there was a typographical error in the regulation itself.

3. Section § 110.108(a)(1)(iii) requires that certain HMOs, in order to demonstrate that they have a fiscally sound operation, submit a financial plan. With the publication on April 9, 1980, at 45 FR 24352-7, of regulations implementing section 1305A of the Act ("Loans and Loan Guarantees for Acquisition and Construction of Ambulatory Health Care Facilities"), the Department will soon be initiating the process of making these awards. Accordingly, § 110.108(a)(1)(iii) has been amended to require an HMO seeking a Federal loan or loan guarantee under section 1305A, as well as certain other HMOs, to submit a financial plan to the Secretary.

4. Section § 110.108(a)(v), which requires the HMO to procure and maintain in force a fidelity bond or bonds in an amount not less than $100,000, has been changed to clarify that the $100,000 minimum is applicable to "each" individual who is entrusted with the handling of the HMO's funds.

5. Sections § 110.108(o)(2)(i) and (3) of the interim regulations required an HMO to furnish to the Secretary the information required to be disclosed under the regulations implementing Sections 1124 and 1902(a)(38) of the Social Security Act, at 42 CFR 420.206 and 42 CFR 455.104, respectively. (These references have been changed to reflect the correct citations.) In the interim regulations, the requirements for the disclosure of this information were inadvertently different: While the Section 1124 information was required to be reported to the Secretary annually, the Section 1902(a)(38) information was required to be reported to the Secretary within 35 days of a request and to HMO members upon reasonable request. In order to treat similarly all of the information required to be disclosed under these provisions of the Social Security Act, the provision in former § 110.108(o)(3) has been combined with § 110.108(o)(2)(i). Section 110.108(o)(2) now requires that the information described above (in addition to the information about significant business transactions with parties in interest) be reported annually to the Secretary and be available to members upon reasonable request. The rest of § 110.108(o) has been renumbered accordingly.

The Assistant Secretary for Health of the Department of Health and Human Services, with the approval of the Secretary of Health and Human Services, amends 42 CFR Part 110, Subpart A, as set forth below.

Dated: June 6, 1980.

**Julius B. Richmond,**

*Assistant Secretary for Health.*

Approved: October 21, 1980.

**Patricia Roberts Harris,**

*Secretary.*

Subpart A is revised to read as follows:

## Subpart A—Requirements for a Health Maintenance Organization

Sec.
110.101 Definitions.
110.102 Health benefits plan: Basic health services.
110.103 Health benefits plan: Supplemental health services.
110.104 Providers of basic and supplemental health services.
110.105 Payment to the HMO for basic health services.
110.106 Payment to the HMO for supplemental health services.
110.107 Availability, accessibility, and continuity of basic and supplemental health services.
110.108 Organization and operation.
110.109 Prohibited activities.
110.110 Special requirements: Titles XVIII and XIX of the Social Security Act.
110.111 Special requirements: Federal employees' health benefits program.

**Authority:** Sec. 215 of the Public Health Service Act, as amended, 58 Stat. 690 (42 U.S.C. 216); secs. 1301-1318 of the Public Health Service Act, as amended, 92 Stat. 2131-2141 (42 U.S.C. 300e-300e-17).

## Subpart A—Requirements for a Health Maintenance Organization

### § 110.101 Definitions.

As used in this part: "Act" means the Public Health Service Act.

"Basic health services" means health services described in § 110.102(a).

"Community rating system" means a system of fixing rates of payments for health services which meets the requirements of § 110.105(a)(3).

"Comprehensive health services" means as a minimum the following services which may be limited as to time and cost:

(1) Physician services (§ 110.102(a)(1));

(2) Outpatient services and inpatient hospital services (§ 110.102(a)(2));

(3) Medically necessary emergency health services (§ 110.102(a)(3)); and

(4) Diagnostic laboratory and diagnostic and therapeutic radiologic services (§ 110.102(a)(6)).

"Direct service contract" means a contract for the provision of basic or supplemental health services or both between an HMO and (1) a health professional other than a member of the staff of the HMO, or (2) an entity other than a medical group or an IPA.

"Full-time student" means a student who is enrolled for a sufficient number of credit hours in a semester or other academic term to enable the student to complete the course of study within not more than the number of semesters or other academic terms normally required to complete that course of study on a full-time basis at the school in which the student is enrolled.

"Health maintenance organization" (HMO) means a legal entity which provides or arranges for the provision of basic and supplemental health services to its members in the manner prescribed by, is organized and operated in the manner prescribed by, and otherwise meets the requirements of, section 1301 of the Act and the regulations of this subpart.

"Health professionals" means physicians (doctors of medicine and doctors of osteopathy), dentists, nurses, podiatrists, optometrists, physicians' assistants, clinical psychologists, social workers, pharmacists, nutritionists, occupational therapists, physical therapists, and other professionals engaged in the delivery of health services who are licensed, practice under an institutional license, are certified, or practice under authority of the HMO, a medical group, individual practice association, or other authority consistent with State law.

"Individual practice association" (IPA) means a partnership, association, corporation, or other legal entity:

(1) Which delivers or arranges for the delivery of health services and which has entered into a written services arrangement or arrangements with health professionals, a majority of whom are licensed to practice medicine or osteopathy. The written services arrangement shall provide:

(i) That these health professionals shall provide their professional services in accordance with a compensation arrangement established by the entity; and

(ii) To the extent feasible:

(A) For the sharing by these health professionals of health (including medical) and other records, equipment, and professional, technical, and administrative staff; and

(B) For the arrangement and encouragement of the continuing education of these health professionals in the field of clinical medicine and related areas.

"Medical group" means a partnership, association, corporation, or other group:

(1) Which is composed of health professionals licensed to practice medicine or osteopathy and of such other licensed health professionals (including dentists, optometrists, and podiatrists) as are necessary for the provision of health services for which the group is responsible;

(2) A majority of the members of which are licensed to practice medicine or osteopathy; and

(3) The members of which:

(i) As their principal professional activity (over 50 percent individually) engage in the coordinated practice of their profession and as a group responsibility have substantial responsibility (over 35 percent in the aggregate of their professional activity) for the delivery of health services to members of an HMO;

(ii) Pool their income from practice as members of the group and distribute it among themselves according to a prearranged salary or drawing account or other similar plan unrelated to the provision of specific health services;

(iii) Share health (including medical) records and substantial portions of major equipment and of professional, technical, and administrative staff;

(iv) Arrange for and encourage continuing education in the field of clinical medicine and related areas for the members of the group and health professionals employed by the group; and

(v) Establish an arrangement whereby a member's enrollment status is not known to the health professional who provides health services to the member.

"Medical group members" means (1) a health professional engaged as a partner, associate, or shareholder in the medical group, or (2) any other health professional employed by the group who may be designated as a medical group member by the medical group.

"Medically underserved population" means the population of an urban or rural area designated by the Secretary as an area with a shortage of personal health services. The Secretary will designate these areas as described in § 110.203(d).

"Member," when used in connection with an HMO, means an individual who has entered into a contractual relationship with the HMO or on whose behalf a contractual arrangement has been entered into with the HMO by a subscriber under which the HMO assumes the responsibility for the provision to the member of basic health services and such supplemental health services as may be contracted for.

"Non-conforming medical group" means an entity which would be a medical group for the purposes of this part but for its failure to satisfy the requirements in paragraph (3)(i) of the definition in this section of "medical group" that the members of a medical group: (1) Spend over 50 percent of their professional time in the coordinated practice of their profession and (2) as a group have substantial responsibility (over 35 percent in the aggregate of their professional time) for the delivery of health services to members of an HMO. Except for purposes of § 110.104(a), regarding the providers of basic health services which an HMO may use, a "non-conforming medical group" shall be considered as a "medical group" for purposes of this subpart.

"Nonmetropolitan area" means an area no part of which is within a standard metropolitan statistical area as designated by the Office of Management and Budget and which does not contain a city whose population exceeds 50,000 individuals.

"Party in interest" means: (1) Any director, officer, partner, or employee of an HMO, any person who is directly or indirectly the beneficial owner of more than 5 percent of the equity of the HMO, any person who is the beneficial owner of a mortgage, deed of trust, note, or other interest secured by, and valuing more than 5 percent of the assets of the HMO, and, in the case of an HMO organized as a nonprofit corporation, an incorporator or member of the corporation under applicable State corporation law;

(2) Any entity in which a person described in paragraph (1)—

(i) Is an officer or director;

(ii) Is a partner (if the entity is organized as a partnership);

(iii) Has directly or indirectly a beneficial interest of more than 5 percent of the equity; or

(iv) Has a mortgage, deed of trust, note, or other interest valuing more than 5 percent of the assets of such entity;

(3) Any member of the immediate family of an individual described in paragraph (1).

"Policymaking body" of an HMO means a board of directors, governing body, or other body of individuals which has the authority to establish policy for the HMO.

"Qualified HMO" means an HMO found by the Secretary to be qualified within the meaning of Section 1310 of the Act and Subpart F of this part.

"Rural area" means any area not listed as a place having a population of 2,500 or more in Document #PC(1)-A, "Number of Inhabitants," Table VI, "Population of Places," and not listed as an urbanized area in Table XI, "Population of Urbanized Areas" of the same document (1970 Census or most recent update of this document, Bureau of Census, U.S. Department of Commerce).

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

"Service area" means the geographic area as defined through zip codes, census tracts, or other geographic subdivisions, found by the Secretary to be the area within which the HMO provides or arranges for basic and supplemental health services that are available and accessible to its members as required by section 1301(b)(4) of the Act.

"Significant business transaction" means any business transaction or series of transactions during any one fiscal year of the HMO, the total value of which exceeds the lesser of $25,000 or 5 percent of the total operating expenses of the HMO.

"Staff of the HMO" means health professionals who are employees of the HMO and who:

(1) Provide services to HMO members at an HMO facility subject to the staff policies and operational procedures of the HMO;

(2) Engage in the coordinated practice of their profession and provide to members of the HMO the health services which the HMO has contracted to provide;

(3) Share medical and other records, equipment, and professional, technical, and administrative staff of the HMO;

(4) Participate in continuing education in their professional field as provided or arranged for by the HMO; and

(5) Provide their professional services in accordance with a compensation arrangement, other than fee-for-service, established by the HMO. This arrangement may include, but is not limited to, fee-for-time, retainer or salary.

"Subscriber" means a member who has entered into a contractual relationship with the HMO or who is responsible for making payments for basic health services (and contracted for supplemental health services) to the HMO or on whose behalf these payments are made.

"Supplemental health services" means the health services described in § 110.103(a).

"Unusual or infrequently used health services" means: (1) Those health services which are projected to involve fewer than 1 percent of the encounters per year for the entire HMO membership, or,

(2) Those health services the provision of which, given the enrollment projection of the HMO and generally accepted staffing patterns, is projected will require less than 0.25 full time equivalent health professionals.

### § 110.102 Health benefits plan: Basic health services.

(a) An HMO shall provide or arrange for the provision of basic health services to its members as needed and without limitations as to time and cost other than those prescribed in the Act and these regulations, as follows:

(1) Physician services (including consultant and referral services by a physician), which shall be provided by a licensed physician, or if a service of a physician may also be provided under applicable State law by other health professionals, an HMO may provide the service through these other health professionals;

(2)(i) Outpatient services, which shall include diagnostic services, treatment services and x-ray services, for patients who are ambulatory and may be provided in a non-hospital based health care facility or at a hospital; (ii) inpatient hospital services, which shall include but not be limited to, room and board, general nursing care, meals and special diets when medically necessary, use of operating room and related facilities, use of intensive care unit and services, x-ray services, laboratory, and other diagnostic tests, drugs, medications, biologicals, anesthesia and oxygen services, special duty nursing when medically necessary, radiation therapy, inhalation therapy, and administration of whole blood and blood plasma; (iii) outpatient services and inpatient hospital services shall include short-term rehabilitation services and physical therapy, the provision of which the HMO determines can be expected to result in the significant improvement of a member's condition within a period of two months;

(3) Instructions to its members on procedures to be followed to secure medically necessary emergency health services both in the service area and out of the service area;

(4) Twenty outpatient visits per member per year, as may be necessary and appropriate for short-term evaluative or crisis intervention mental health services, or both;

(5) Diagnosis, medical treatment and referral services (including referral services to appropriate ancillary services) for the abuse of or addiction to alcohol and drugs:

(i) Diagnosis and medical treatment for the abuse of or addiction to alcohol and drugs shall include detoxification for alcoholism or drug abuse on either an outpatient or inpatient basis, whichever is medically determined to be appropriate, in addition to the other required basic health services for the treatment of other medical conditions;

(ii) Referral services may be either for medical or for nonmedical ancillary services. Medical services shall be a part of basic health services; nonmedical ancillary services (such as vocational rehabilitation and employment counseling) and prolonged rehabilitation services in a specialized inpatient or residential facility need not be a part of basic health services;

(6) Diagnostic laboratory and diagnostic and therapeutic radiologic services in support of basic health services;

(7) Home health services provided at a member's home by health care personnel, as prescribed or directed by the responsible physician or other authority designated by the HMO; and

(8) Preventive health services, which shall be made available to members and shall include at least the following:

(i) A broad range of voluntary family planning services;

(ii) Services for infertility;

(iii) Well-child care from birth;

(iv) Periodic health evaluations for adults;

(v) Eye and ear examinations for children through age 17, to determine the need for vision and hearing correction; and

(vi) Pediatric and adult immunizations, in accord with accepted medical practice.

(b) In addition, an HMO may include a health service described in § 110.103 as a supplemental health service in the basic health services which it provides or arranges for its members for a basic health services payment.

(c) To the extent that a natural disaster, war, riot, civil insurrection, epidemic or any other emergency or similar event not within the control of an HMO results in the facilities, personnel, or financial resources of an HMO being unavailable to provide or arrange for the provision of a basic or supplemental health service in accordance with the requirements of this subpart, the HMO is required only to make a good-faith effort to provide or arrange for the provision of the service, taking into account the impact of the event. For purposes of this paragraph, an event is not within the control of an HMO if the HMO cannot exercise influence or dominion over its occurrence.

(d) The following are not required to be provided as basic health services:

(1) Corrective appliances and artificial aids;

(2) Mental health services, except as required under section 1302(1)(D) of the Act and paragraph (a)(4) of this section;

(3) Cosmetic surgery, unless medically necessary;

(4) Prescribed drugs and medicines incidental to outpatient care;

(5) Ambulance services, unless medically necessary;

(6) Care for military service connected disabilities for which the member is legally entitled to services and for which facilities are reasonably available to this member;

(7) Care for conditions that State or local law requires be treated in a public facility;

(8) Dental services;

(9) Vision and hearing care except as required by sections 1302(1)(A) and 1302(1)(H)(vi) of the Act and paragraphs (a)(1) and (a)(8) of this section;

(10) Custodial or domiciliary care;

(11) Experimental medical, surgical, or other experimental health care procedures, unless approved as a basic health service by the policymaking body of the HMO;

(12) Personal or comfort items and private rooms, unless medically necessary during inpatient hospitalization;

(13) Whole blood and blood plasma;

(14) Long-term physical therapy and rehabilitation;

(15) Durable medical equipment for home use (such as wheel chairs, surgical beds, respirators, dialysis machines); and

(16) Health services which are unusual and infrequently provided and not necessary for the protection of individual health, as approved by the Secretary upon application by the HMO.

(e) An HMO may not offer to provide or arrange for the provision of basic health services on a prepayment basis which do not include all the basic health services set forth in paragraph (a) of this section or which are limited as to time and cost except in a manner prescribed by this part.

**§ 110.103 Health benefits plan: supplemental health services.**

(a) Each HMO may provide to its members any of the following health services, which may be limited as to time and cost:

(1) Services of facilities for intermediate and long-term care;

(2) Vision and hearing care not included as a basic health service;

(3) Dental services;

(4) Mental health services not included as a basic health service;

(5) Long-term physical medicine and rehabilitative services (including physical therapy);

(6) Prescription drugs prescribed in the course of the provision by the HMO of basic outpatient or supplemental health services; and

(7) Other health services which are not included as basic health services.

(b) An HMO shall determine the level and scope of supplemental health services included with basic health services provided to its members for a basic health services payment or those services offered to its members as supplemental health services.

(c) An HMO is authorized, in connection with the prescription or provision of prescription drugs, to: (1) Maintain, review, and evaluate a drug use profile of its members receiving these services, (2) evaluate patterns of drug utilization to assure optimum drug therapy, and (3) provide for instruction of its members and of health professionals in the use of prescription and non-prescription drugs. Each HMO providing these services shall insure that:

(i) The program is developed jointly by the physicians and pharmacists associated with the HMO;

(ii) The objectives of the program are explained to all health professionals and members of the HMO;

(iii) Individual rights are protected and that all information regarding and identifying an individual is available only to appropriate health professionals of the HMO and to the individual member at his request;

(iv) The primary thrust of the program is optimum drug therapy for the individual member of the HMO; and

(v) The information obtained in drug utilization review is utilized in educational programs for health professionals and members of the HMO.

**§ 110.104 Providers of basic and supplemental health services.**

(a)(1) The HMO shall provide that the services of health professionals which are provided as basic health services will, except as provided in paragraph (e) of this section, be provided or arranged for through (i) health professionals who are staff of the HMO, (ii) a medical group or groups, (iii) an IPA or IPAs, (iv) physicians or other health professionals under direct service contracts with the HMO for the provision of these services, or (v) any combination of staff, medical group or groups, IPA or IPAs, or physicians or other health professionals under direct service contracts with the HMO.

(2) A staff or medical group model HMO may have as providers of basic health services physicians who have also entered into written services arrangements with an IPA or IPAs, but only if either (i) these physicians number less than 50 percent of the physicians who have entered into arrangements with the IPA or IPAs, or (ii) if the sharing is 50 percent or greater, the Secretary approves the sharing as being consistent with the purposes of section 1310(b) of the Act.

(3) Within the 4 year period beginning with the month following the month in which an HMO becomes a qualified HMO, physician services which are basic health services may also be provided by a non-conforming medical group. After this 4 year period, the HMO may use this entity to provide physician services which are basic health services only if (i) the entity meets the definition of medical group in § 110.101, or (ii) the Secretary determines that the principal professional activity (over 50 percent individually) of the entity's members is the coordinated practice of their profession, and if the HMO has demonstrated to the satisfaction of the Secretary that the entity is committed to the delivery of medical services on a prepaid group practice basis by either:

(A) Presenting a reasonable time-phased plan for the entity to achieve compliance with the "substantial responsibility" requirement of Subparagraph (3)(i) of the definition of "medical group" in § 110.101. The HMO shall update the plan annually and shall demonstrate to the satisfaction of the Secretary that the entity is making continuous efforts and progress towards compliance with the requirements of the definition of "medical group," or,

(B) Demonstrating that compliance by the entity with the "substantial responsibility" requirement is unreasonable or impractical because *(1)* the HMO serves a non-metropolitan or rural area as defined in § 110.101, or *(2)* the entity is a multi-specialty group which provides medical consultation upon referral on a regional or national basis, or *(3)* the majority of the residents of the HMO's service area are not eligible for employer-employee health benefits plans and the HMO has an insufficient number of members to require utilization of at least 35 percent of the entity's services.

(b) After the expiration of the first fiscal years of an HMO beginning after the month in which it become a qualified HMO, the HMO may not, in any fiscal year, enter into contracts for basic and supplemental health services with physicians other than members of staff, medical groups, of IPAs if the amounts paid under these contracts exceed (1) 15 percent of the total estimated amount to be paid in that fiscal year by the HMO to physicians for the provision of basic and supplemental health services by physicians, or (2) if the HMO principally serves a rural area, 30 percent of that amount. However, this paragraph does not apply to payments under a contract for the purchase of physician services from a non-conforming medical group that meets the conditions set forth in § 110.104(a)(3)(ii).

(c) HMOs shall include: (1) In their contracts with medical groups or IPAs for the provision of basic and supplemental health services at least the following:

(i) A description of responsibilities of the parties to the contract;

(ii) The agreed upon compensation for services;

(iii) An agreement that the medical group or IPA, its members and the health professionals contracting with it, will look solely to the HMO for compensation for services provided to the HMO's members. This agreement shall not extend to copayments or payments for supplemental health services on other than a prepaid basis, but the contracting party shall not assert any claim for compenstion against members in excess of these copayments or payments for these supplemental health services;

(iv) Provisions requiring participation by health professionals in quality assurance activities;

(v) A description of mechanisms, such as risk sharing, financial incentives, or other incentives, to be applied to monitor utilization and to control costs of basic and supplemental health services and to achieve utilization goals; and

(vi) Assurances that medical groups and IPAs, or the health professionals associated with them, will be protected by professional liability coverage, either through insurance or self-insurance;

(2) In their contracts with health professionals for the provision of basic and supplemental health services (except for unusual or infrequently used services) at least the following:

(i) The provisions described in paragraphs (c)(1)(i), (ii), (iii), and (iv) of this section; and

(ii) Provisions requiring appropriate continuing education.

(d) Staff model HMOs shall have effective procedures to monitor utilization and to control cost of basic and supplemental health services, and to achieve utilization goals.

(e) Paragraph (a) of this section does not apply to the provision of the services of a physician—

(1) Which the HMO determines are unusual or infrequently used services; or

(2) Which, because of an emergency, it was medically necessary to provide to the member other than as required by paragraph (a) of this section; or

(3) Which are provided as part of the inpatient hospital services by employees or staff of a hospital or provided by staff of other entities such as community mental health centers, home health agencies, visiting nurses' associations, independent laboratories, or family planning agencies.

(f) Supplemental health services shall be provided or arranged for by the HMO and need not be provided by providers of basic health services under contract with the HMO.

(g) Each HMO shall:

(1) Pay the provider, or reimburse its members for the payment of reasonable charges for basic health services (or supplemental health services which the HMO agreed to provide on a prepayment basis) for which its members have contracted, which were medically necessary and immediately required to be obtained other than through the HMO because of an unforeseen illness, injury, or condition, as determined by the HMO;

(2) Adopt procedures to review promptly all claims from members for reimbursement for the provision of health services described in paragraph (g)(1) of this section, including a procedure for the determination of the medical necessity for obtaining the services other than through the HMO; and

(3) Provide instructions to its members on procedures to be followed to secure these health services.

### § 110.105 Payment for basic health services.

(a) *Basic health services payment.* Each HMO shall provide or arrange for the provision of basic health services for a basic health services payment which:

(1) Is to be paid on a periodic basis without regard to the dates these services are provided;

(2) Is fixed without regard to the frequency, extent, or kind of basic health services actually furnished;

(3) Except as provided in paragraph (c) of this section, is fixed under a community rating system, as described in paragraph (b) of this section; and

(4) May be supplemented by nominal copayments which may be required for the provision of specific basic health services. Each HMO may establish one or more copayment options calculated on the basis of a community rating system.

(i) An HMO may not impose copayment charges that exceed 50 percent of the total cost of providing any single service to its members, nor in the aggregate more than 20 percent of the total cost of providing all basic health services.

(ii) To insure that copayments are not a barrier to the utilization of health services or membership in the HMO, an HMO may not impose copayment charges on any subscriber (or members covered by the subscriber's contract with the HMO) in any calendar year, when the copayments made by the subscriber (or members) in that calendar year total 100 percent of the total annual premium cost which that subscriber (or members) would be required to pay if he (or they) were enrolled under an option with no copayments. This limitation applies only if the subscriber (or members) demonstrates that copayments in that amount have been paid in that year.

(b) *Community rating system.* Under a community rating system, rates of payment for health services may be determined on a per-person or per-family basis and may vary with the number of persons in a family. Except as otherwise authorized in this paragraph, these rates must be equivalent for all individuals and for all families of similar composition. Rates of payment may be based on either a schedule of rates charged to each subscriber group or on a per-member-per-month (or per-subscriber-per-month) revenue requirement for the HMO. In the former event, rates may vary from group to group if the projected total revenue from each group is substantially equivalent to the revenue which would be derived if the schedule of rates were uniform for all groups. In the latter event, the payments from each group of subscribers shall be calculated to yield revenues substantially equivalent to the product of the total number of members (or subscribers) expected to be enrolled from the group and the per-member-per-month (or per-subscriber-per-month) revenue requirement for the HMO. In addition, a community rating system must meet the following requirements:

(1) Rates of payment may not vary because of actual or anticipated utilization of services by individuals associated with any specific group of subscribers. These provisions do not preclude changes in the rates of payment which are established for new enrollments or reenrollments and which do not apply to existing contracts until the renewal of these contracts.

(2) Rates of payment shall reflect differences in benefits and copayment requirements.

(3) The following differentials may be established under a community rating system.

(i) Nominal differentials in rates may be established to reflect differences in marketing costs and the different administrative costs of collecting payments from the following categories of potential subscribers:

(A) Individual (nongroup) subscribers (including their families).

(B) Small groups of subscribers (100 subscribers or fewer).

(C) Large groups of subscribers (over 100 subscribers).

(ii) Differentials in rates may be established for subscribers enrolled in a HMO: (A) Under a contract with a governmental authority under section 1079 ("Contracts for Medical Care for Spouses and Children: Plans") or section 1086 ("Contracts for Health Benefits for Certain Members, Former Members and their Dependents") of Title 10 ("Armed Forces"), United States Code; or (B) under any other governmental program (other than the health benefits program authorized by chapter 89 ("Health Insurance") of Title 5 ("Government Organization and Employees"), United States Code; or (C) under any health benefits program for employees of States, political subdivision of States, and other public entities.

(iii) an HMO may establish a separate community rate for separate regional components of the organization upon satisfactory demonstration to the Secretary of the following:

(A) Each regional component is geographically distinct and separate from any other regional component; and

(B) Each regional component provides substantially the full range of basic health services to its members, without extensive referral between components of the organization for these services, and without substantial utilization by any two components of the same health care facilities. The separate community rate for each regional component of the HMO must be based on the different costs of providing health services in the respective regions.

(c) *Exceptions to community rating requirement.* (1) In the case of an HMO which provided comprehensive health services on a prepaid basis before it became a qualifed HMO, the requirement of community rating shall not apply to the HMO during the forty-eight month period beginning with the month following the month in which it became a qualifed HMO.

(2) The requirement of community rating does not apply to the basic health services payment for basic health services provided a member who is a full-time student at an accredited institution of higher education.

(d) *Charges for benefits covered by workers' compensation law or insurance policy.* The requirements respecting the basic health services payment do not apply to the provision of basic health services to a member for an illness or injury for which the member is entitled to benefits under a workers' compensation law or an insurance policy, but only to the extent these benefits apply to these services.

(1) For the provision of services for an illness or injury for which a member is entitled to benefits under a workers' compensation law, the HMO may, if authorized by this law, charge or authorize the provider of the services to charge, in accordance with the charges allowed under the law:-(i) The insurance carrier, employer, or other entity which under the law is to pay for the provision of the services, or (ii) the member, to the extent that the member has been paid under the law for the services.

(2) For the provision of services for an illness or injury for which a member is entitled to benefits under an insurance policy, an HMO may charge or authorize the provider of the services to charge: (i) The insurance carrier under the policy, or (ii) the member, to the extent that the member has been paid under the policy for the services.

(e) *Late payment penalty.* HMOs may charge a late payment penalty on accounts receivable which are in arrears.

### § 110.106 Payment for supplemental health services.

(a) An HMO may require supplemental health services payments, in addition to the basic health services payments, for the provision of each health service included in the supplemental health services set forth in § 110.103 for which subscribers have contracted, or it may include supplemental health services in the basic health services provided its members for a basic health services payment.

(b) Supplemental health services payments may be made in any agreed upon manner, such as prepayment or fee-for-service. Supplemental health services payments which are fixed on a prepayment basis, however, shall be fixed under a community rating system, unless the supplemental health services payment is for a supplemental health service provided a member who is a full-time student at an accredited institution of higher education. In the case of an HMO which provided comprehensive health services on a prepaid basis before it became a qualifed HMO, the community rating requirement shall not apply to that HMO during the forty-eight month period beginning with the month following the month in which it became a qualifed HMO.

(c) When the HMO provides supplemental health services on a prepayment basis for which the member is entitled to benefits under a workers' compensation law or an insurance policy, the HMO may take the actions described in § 110.105(d)(1) or (2) (respecting charges for basic health services which are benefits under a workers' compensation law or insurance policy) as appropriate.

### § 110.107 Availability, accessibility, and continuity of basic and supplemental health services.

Within the HMO's service area, basic health services and those supplemental health services for which members have contracted shall be:

(a) Provided or arranged for by the HMO;

(b) Available and accessible to each of the HMO's members promptly as appropriate with respect to:

(1) Geographic location, hours of operation, and provisions for after-hours services (medically necessary emergency services must be available and accessible 24 hours a day, 7 days a week); and

(2) Staffing patterns within generally accepted norms for meeting the projected membership needs; and

(c) Provided in a manner which assures continuity, including but not limited to:

(1) Provision of a health professional who is primarily responsible for coordinating the member's overall health care; and

(2) Development of a health (including medical) recordkeeping system through which pertinent information relating to the health care of the patient is accumulated and is readily available to appropriate professionals.

### § 110.108 Organization and operation.

(a) *Fiscally sound operation and administrative and managerial arrangements.* (1) Each HMO shall have a fiscally sound operation as demonstrated by:

(i) Total assets being greater than total unsubordinated liabilities. In this evaluation, loan funds awarded or guaranteed under section 1305 of the Act are not included as liabilities, and if the funds have not been disbursed to the HMO by the Secretary or by an escrow agent, they are not included as assets;

(ii) Sufficient cash flow and adequate liquidity to meet obligations as they become due;

(iii) A net operating surplus. If the HMO has not earned a cumulative net operating surplus during the three most recent fiscal years, did not earn a net operating surplus during the most recent fiscal year, does not a have positive net worth, or is seeking a Federal loan or loan guarantee under sections 1305 or 1305A of the Act, the HMO shall submit a financial plan satisfactory to the Secretary to achieve net operating surplus within available fiscal resources. This plan shall include:

(A) A detailed marketing plan;

(B) Statements of revenue and expense on an accrual basis;

(C) Sources and uses of funds' statements; and

(D) Balance sheets;

(iv) A plan for handling insolvency which allows for continuation of benefits for the duration of the contract period for which payment has been made, continuation of benefits to members who are confined on the date of insolvency in an inpatient facility until their discharge, and payments to unaffiliated providers for services rendered;

(v) A fidelity bond or bonds, procured and maintained by the HMO, in an amount fixed by its policymaking body but not less than $100,000 per individual, covering each officer and employee entrusted with the handling of its funds. The bond may have reasonable deductibles, based upon the financial strength of the HMO;

(vi) Insurance policies or other arrangements, secured and maintained by the HMO and approved by the Secretary to insure the HMO against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks; and

(vii) A plan to maximize its enrollment in a manner consistent with sound management.

(2) Each HMO shall have administrative and mangerial arrangements satisfactory to the Secretary, as demonstrated by at least the following:

(i) A policymaking body which exercises oversight and control over the HMO's policies and personnel to assure that management actions are in the best interest of the HMO and its membership; and

(ii) Personnel and systems sufficient for the HMO to organize, plan, control and evaluate the financial, marketing, health services, quality assurance program, administrative and management aspects of the HMO. At a minimum, the HMO shall be managed by an executive whose appointment and removal are under the control of the HMO's policymaking body.

(b) *Financial risk.* Each HMO shall assume full financial risk on a prospective basis for the provision of basic health services, except that it may obtain insurance or make other arrangements: (1) For the cost of providing to any member basic health services the aggregate value of which exceeds $5,000 in any year;

(2) For the cost of basic health services provided to its members other than through the HMO because medical necessity required their provision before they could be secured through the HMO; and

(3) For not more than 90 percent of the amount by which its costs for any of its fiscal years exceed 115 percent of its income for that fiscal year.

(c) *Broadly representative enrollment.* After full and fair disclosure of its benefits, coverage, rates, grievance procedures, location, and hours of service, and a general description of its participating providers and financial condition, each HMO shall offer enrollment to persons who are broadly representative of the various age, social, and income groups within its device area. In the case of an HMO which has a medically underserved population located in its service area, not more than 75 percent of the HMO members may be enrolled from the medically underserved population unless the area in which that population resides is also a rural area.

(d) *Open enrollment.* If the HMO has either provided comprehensive health services on a prepaid basis for a period of at least 5 years or has an enrollment of at least 50,000 members, it shall have an open enrollment period at least once during the fiscal year next following each fiscal year in which it did not have a financial deficit. (For purposes of this paragraph, financial deficits must be reported and certified by an independent Certified Public Accountant.) The period of open enrollment shall be determined under paragraph (d)(1) of this section. During open enrollment, the HMO shall accept individuals for membership in the order in which they apply for enrollment and, except as provided in paragraph (d)(2) of this section, without regard to preexisting illness, medical condition, or degree of disability.

(1) An open enrollment period for an HMO shall be the lesser of—

(i) 30 days, or

(ii) The number of days in which the organization enrolls a number of individuals at least equal to 3 percent of its total net increase in enrollment (if any) in the fiscal year preceding the fiscal year in which the open enrollment period is held. In determining the total net increase in enrollment in an HMO, the HMO need not include any individual who is (A) enrolled in the HMO through a group which had a contract or other arrangement for health care services with the HMO when the HMO was determined to be a qualified HMO, or (B) entitled to insurance benefits under Title XVIII of the Social Security Act or to medical assistance under a State plan approved under Title XIX of that Act and was enrolled in the HMO when the HMO was determined to be a qualified HMO.

(2) An HMO is not required to enroll individuals who are confined to an institution because of (i) chronic illness, (ii) permanent injury, or (iii) other infirmity which would cause economic impairment to the HMO, as demonstrated to the satisfaction of the Secretary, if these individuals were enrolled.

(3) And HMO may defer the effective date of benefits for individuals enrolled under this paragraph for up to 90 days after the date of enrollment.

(4) An HMO may require an individual applying for membership at periods other than the required annual open enrollment period to submit to and pay for a health status questionnaire or a health examination. An HMO may deny enrollment based on results of this questionnaire or health examination.

(5) The Secretary may, under paragraph (e) of this section, waive the requirements of this paragraph for an HMO which demonstrates that compliance with the provisions of this paragraph would jeopardize its economic viability.

(e) *Waiver of open enrollment.* In order to obtain a waiver under paragraph (d)(5) of this section, the HMO shall submit documentation that it has prospectively determined on an actuarial basis, using data available in the area or from similar organizations elsewhere, that the average utilization of services of potential individual members would so increase costs as to jeopardize the economic viability of the organization if it maintained an open enrollment period.

(f) *Health status and enrollment.* The HMO shall not expel or refuse to re-enroll any member nor refuse to enroll individual members of a group, on the basis of the health status, health care needs, or age of the member or individual. For purposes of this paragraph, a "group" is an entity which consists of members who enroll in the HMO through a contract or other arrangement which provides for the enrollment of two or more subscribers. Nothing in this subpart prohibits an HMO from requiring that, as a condition of continued eligibility for membership, dependents of a subscriber, upon reaching a specified age, convert to nongroup membership consistent with the terms of § 110.108(g).

(g) *Conversion of membership.* Each HMO shall offer membership on the same terms and conditions as are available to a nongroup subscriber to:

(1) Each subscriber (and his enrolled dependents) leaving a group; and

(2) Each member who would otherwise cease to be eligible for HMO membership because of his or her age or the death or divorce of a subscriber.

(h) *Policymaking body.* (1) In the case of a private HMO, no later than one year after becoming operational as a qualified HMO, at least one-third of the membership of its policymaking body must be members of the HMO who reside in or in proximity to the service area of the HMO. An HMO with regional components and one overall policymaking body must assure that the individuals satisfying the one-third member requirement reside in, or in proximity to, the service area of at least one of the HMO's regional components. HMOs with policymaking bodies consisting of the same individuals must assure that the individuals satisfying the one-third member requirement reside in, or in proximity to, the service area of at least one of the HMOs.

(i) No member having ownership of or financial interest in, or employed by, or gaining financial reward from direct dealings with, the HMO or a plan-affiliated institution or organization, and no members of the immediate family of such member shall be included in the minimum one-third member representation on the policymaking body. However, none of the foregoing prohibits the payments of directors' fees or other similar fees, or interest and dividends derived from membership in an HMO cooperative, to persons serving on the policymaking body.

(ii) There shall be equitable representation on the member portion of the policymaking body of members from the medically underserved populations served by the HMO in proportion to their enrollment relative to the entire enrollment; except that if the membership from these medically underserved populations is at least 5 percent of the total enrollment, then those populations shall not be without representation.

(2) In the case of public HMO, have an advisory board to its policymaking body operating the HMO which board meets the requirements of subparagraph (1) of this paragraph, and to which may be delegated policymaking authority for the HMO.

(i) *Grievance procedures.* Each HMO shall have and use meaningful procedures for hearing and resolving grievances between the HMO (including the staff of the HMO, the medical group, and the IPA) and the members of the HMO. These procedures must assure that: (1) Grievances and complaints will be transmitted in a timely manner to appropriate decisionmaking levels within the HMO which have authority to take corrective action; and (2) appropriate action will be taken promptly, including a full investigation if necessary and notification of concerned parties as to the results of the HMO's investigation.

(j) *Quality assurance program.* Each HMO shall have an ongoing quality assurance program for is health services which:

(1) Stresses health outcomes to the extent consistent with the state of the art;

(2) Provides review by physicians and other health professionals of the process followed in the provision of health services;

(3) Uses systematic data collection of performance and patient results, provides interpretation of these data to its practitioners, and institutes needed change; and

(4) Includes written procedures for taking appropriate remedial action whenever, as determined under the quality assurance program, inappropriate or substandard services have been provided or services which should have been furnished have not been provided;

(k) *Certification of institutional providers.* Each HMO shall assure that institutional providers through which it provides basic and supplemental health services (1) are certified either under Title XVIII of the Social Security Act (Medicare) in accordance with 42 CFR Part 405 or under Title XIX of the Social Security Act (Medicaid) in accordance with the regulations governing participation of providers in the Medical Assistance Program; or (2) in the case of hospitals, are either accredited by the Joint Commission on Accreditation of Hospitals or certified by Medicare; or (3) in the case of clinical laboratories (except for laboratories exempted from section 353 of the Public Health Service Act by paragraphs (d)(2), (i), or (1) of that section), certified by Medicare or Medicaid or licensed under section 353.

(l) *Continuing education of health professionals.* Each HMO shall provide, or make arrangements for, continuing education for its health professional staff;

(m) *Health education.* In support of the provision of health services, each HMO shall actively provide its members:

(1) Health education services including instruction in personal health care measures;

(2) Information about its services, including education on generally accepted medical standards for use and frequency of its services; and

(3) Nutritional education and counseling;

(n) *Medical social services.* In support of the provision of health services, each HMO shall offer its members medical social services, which shall include appropriate assistance in dealing with the physical, emotional and economic impact of illness and disability. These services may include pre- and post-hospitalization planning, referral to services provided through community health and social welfare agencies, and related family counseling;

(o) *Reporting and disclosure requirements.* (1) While safeguarding the confidentiality of the doctor-patient relationship, each HMO shall provide an effective procedure to develop, compile, evaluate, and report to the Secretary, to its members, and to the general public, at the times and in the manner the Secretary requires, statistics and other information relating to:

(i) The cost of its operations;

(ii) The patterns of utilization of its services;

(iii) The availability, accessibility, and acceptability of its services;

(iv) To the extent practical, developments in the health status of its members;

(v) Information demonstrating that the HMO has a fiscally sound operation;

(vi) Other matters as the Secretary may require;

(2) Each HMO shall report to the Secretary annually, within 180 days of the end of its fiscal year (unless for good cause shown, the Secretary authorizes an extension of time):

(i) The information required to be reported by disclosing entities under regulations implementing section 1124 and section 1902(a)(38) of the Social Security Act (see 42 CFR 420.206 and 42 CFR 455.104), respectively.

(ii) A description of the following significant business transactions between the HMO and a party in interest, and a justification that the costs of these transactions do not exceed the costs which would be incurred if these transactions were to be with someone who is not a party in interest (or if they do, a justification that the higher costs are consistent with prudent management and fiscal soundness requirements):

(A) Sale, exchange, or leasing of property;

(B) Furnishing for consideration of goods, services (including management services, but excluding health services provided to members by staff, medical groups, IPAs, or any combination thereof and services provided by employees of the HMO in the normal course of their employment), or facilities; and

(C) Lending of money or other extension of credit.

(3)(i) Report to the Secretary annually, within 180 days of the end of its fiscal year (unless for good cause shown, the Secretary authorizes an extension of time), a combined financial statement for the organization and such entity if:

(A) Thirty-five percent or more of the costs of operation of the HMO go to a party in interest; or

(B) Thirty-five percent or more of the revenue of a party in interest is from the HMO.

The combined financial statements must display in separate columns the financial information for the HMO and each of these parties in interest. Inter-entity transactions must be eliminated in the consolidated column. These statements must have been examined by an independent auditor in accordance with generally accepted accounting principles, and must include appropriate opinions and notes.

(ii) The Secretary may, upon a written request from an HMO and for good cause shown, waive the requirement that its combined financial statement include the financial information required in this paragraph with respect to a particular entity.

(p) *Human diginity.* Each HMO shall be organized and operated in a manner intended to preserve human dignity;

(q) *Confidentiality of health records.* Each HMO shall establish adequate procedures to insure confidentiality of its members' Health (including medical) records; and

(r) *Referral information.* Each HMO shall make arrangements either directly or through its providers to assure that the HMO or the health professional coordinating the member's overall health care is kept informed about the services provided to its members by referral resources.

### § 110.109 Prohibited activities.

An HMO may not sell, market or promote, to an individual or group, directly or through arrangements with other entities, health insurance or a health service benefit plan for health benefits which the HMO includes in the prepaid health benefits package offered to that individual or group. In addition, the HMO may not permit its employees to do so in the normal course of their employment.

### § 110.110 Special requirements: Titles XVIII and XIX of the Social Security Act.

(a) As provided in section 1307(d) of the Act, an HMO which otherwise complies with section 1301(b) and section 1301(c) of the Act, and with the applicable regulations of this subpart, and which enrolls members who are entitled to insurance benefits under Title XVIII of the Social Security Act or to medical assistance under a State plan approved under Title XIX of that Act, may still be considered as an HMO, if with respect to its Title XVIII and Title XIX members it provides services and is operated as required by Title XVIII or XIX, as appropriate, and regulations thereunder.

(b) Notwithstanding any inconsistent requirements of this subpart, an HMO which enters into a contract with the Secretary under Title XVIII of the Social Security Act or with a State under Title XIX of that Act shall, with respect to its members entitled to insurance benefits or medical assistance under those titles, comply with the applicable Title XVIII or Title XIX requirements, including deductible and coinsurance requirements, enrollment mix and enrollment practice requirements, in accordance with the provisions of Title XVIII or the Title XIX State plan of the State with which it is contracting. Copayment options which are not in accordance with a Title XIX State plan may not be imposed on Title XIX enrollees.

(c) Any grievance procedures authorized under Title XVIII or Title XIX of the Social Security Act are not superseded by the provisions of § 110.108(i).

### § 110.111 Special requirements: Federal employee health benefits program.

An entity which provides health services to a defined population on a prepaid basis and which has members who are enrolled under the health benefits program authorized by chapter 89 of Title 5, United States Code, may be considered as an HMO for purposes of receiving assistance under this Part if with respect to its other members it (a) provides health services in accordance with section 1301(b) of the Act and the applicable regulations of this part and (b) is organized and operated in the manner prescribed by section 1301(c) of the Act and the applicable regulations of this part.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Public Health Service

## 42 CFR Part 110

## Health Maintenance Organizations; Federal Financial Assistance: General

**AGENCY:** Public Health Service, HHS.

**ACTION:** Final regulations.

**SUMMARY:** This document amends the general requirements for the award of grants, loans and loan guarantees to public and private entities under Title XIII of the Public Health Service Act (the Act). It sets forth (1) a condition that the Secretary may impose with respect to the approval of any application for a feasibility study or for a project for the planning or initial development of a health maintenance organization (HMO), and (2) a number of technical revisions to conform these regulations with the Department's grant administration requirements of 45 CFR Part 74.

**EFFECTIVE DATE:** These amendments are effective on August 18, 1980.

**FOR FURTHER INFORMATION CONTACT:** Howard R. Veit, Director, Office of Health Maintenance Organizations, Park Building 3rd Floor, 12420 Parklawn Drive, Rockville, Maryland 20857, 301/443-4106.

**SUPPLEMENTARY INFORMATION:** On July 18, 1979, final regulations were published in the **Federal Register** (44 FR 42074-9) to amend 42 CFR Part 110, Subpart B. Subpart B sets forth general provisions which apply to Federal financial assistance for the development and operation of HMOs. In the preamble to the July 18 regulations, the Secretary of Health and Human Services (HHS; at that time, Health, Education, and Welfare) also invited comments on a proposal to add a requirement that for awards made under sections 1303 and 1304 of the Act (feasibility studies and planning and initial development projects), one element of an approvable application would be that the project director be approved by the Secretary. Interested persons were invited to submit written comments on this proposed amendment by September 17, 1979. Five organizations submitted comments.

One commenter opposed the proposal on the ground that it "inappropriately usurps a legitimate prerogative of an applicant organization to select, and to change the person who will act as project director." A second commenter expressed concern that imposition of this requirement would result in delays in appointing project directors. The other three commenters supported the proposal that the Secretary have the right to approve the project director.

As to the ability to select and replace the project director, the Department has decided to amend 42 CFR 110.206 (now § 110.205) by adding a new paragraph (b), stating that, with respect to feasibility, planning and initial development activities funded under Title XIII of the Act, the Secretary may reserve the right to approve the project director. Thus, the rule does not require that every project director be approved by the Secretary. Rather, the rule gives the Secretary the authority to reserve, as to any particular applicant, the right to approve the project director. Accordingly, the Department emphasizes that entities assisted under sections 1303 and 1304 of the Act will still be able both to select and to replace the project director, subject in certain cases to the Secretary's right to approve the selection or replacement.

As to the potential for delay, the Department anticipates that it should be able, in most cases, to exercise its right of approval as part of the normal process of reviewing the application for assistance. In any event, the Department notes its experience that the competence of the project director is one of the major factors in determining whether a project is accomplished successfully. Thus, it believes that, in those cases where the Secretary has reserved the right to approve the project director, the importance of ensuring that the entity has a competent project director outweighs any potential administrative inconvenience.

Several technical revisions have also been made in these regulations to conform with the Department's grant administration regulations at 45 CFR Part 74. These changes are:

1. Deletion of § 110.205, "What records must be maintained and what reports must be submitted?". This section duplicates provisions in 45 CFR Part 74 which applies to grants funded under this part. As to loans and loan guarantees, these provisions are contained in the applicable loan documents. Accordingly, § 110.206 is renumbered as § 110.205.

2. Deletion of § 110.207, "What are the government's rights with respect to data developed during the term of Federal financial assistance?". This section also duplicates provisions in 45 CFR Part 74. As to loans and loan guarantees, the Department has determined that, in general, it is not appropriate to impose the requirements with respect to data developed during the term of Federal financial assistance. Accordingly, § 110.208 is renumbered as § 110.206.

3. Section 110.209 (now § 110.207) sets forth the other HHS regulations that are applicable to grants and those that are applicable to loans and loan guarantees awarded under this part. It is revised to clarify that the references to other applicable HHS regulations are not intended to be an exclusive list of what other regulations may apply to recipients of awards under this Part. The section has also been revised to add the following to the list of HHS regulations that, among others, are applicable to awards made under this Part: (a) 42 CFR Part 50, Subpart D—Public Health Service grant appeals procedures (applicable to grants only), (b) 45 CFR Part 81—Practice and procedures for hearings under Part 80, and (c) 45 CFR Part 90—Nondiscrimination on the basis of age in programs or activities receiving Federal financial assistance from HHS.

4. A new § 110.208 is added to set forth clearly the purposes for which grant funds awarded under this Part may be used.

5. Section 110.210 (now § 110.209) is now entitled, "What is the effect of a grantee's failure to become or remain a qualified HMO?" It is also corrected to bring it into conformity with grant administration regulations at 45 CFR Part 74 which relate to the accountability of grantees.

6. Section 110.211 (now § 110.210) is revised to provide clear guidance to grantees and recipients of loans and loan guarantees as to the obligation of the Federal Government to make additional awards.

7. Section 110.212 is renumbered as § 110.211.

(Sec. 215, 58 Stat. 690 (42 U.S.C. 216); secs. 1301-1318, as amended, 92 Stat. 2131-2141 (42 U.S.C. 300e-300e-17))

Dated: June 11, 1980.

**Julius B. Richmond,**
*Assistant Secretary for Health.*

Approved: August 7, 1980.

**Patricia Roberts Harris,**
*Secretary.*

42 CFR Part 110, Subpart B, is revised as follows:

### § 110.205 [Deleted]

(1) Delete § 110.205.

### § 110.206 [Renumbered as § 110.205 and Amended]

(2) Section 110.206 is renumbered § 110.205 with existing text designated paragraph (a) and new paragraph (b) is added as follows: "(b) In approving any application under Section 1303 or 1304 of the Act for feasibility, planning, or initial development, the Secretary may

reserve the right to approve the project director."

### § 110.207 [Deleted]

(3) Delete § 110.207.

### § 110.208 [Renumbered as § 110.206]

(4) Section 110.208 is renumbered as § 110.206.

(5) Section 110.209 is renumbered as § 110.207 and is revised to read:

### § 110.207 What other HHS regulations apply?

(a) Several other HHS regulations apply to grants under this Part. These include, but are not limited to:

42 CFR Part 50, Subpart D—Public Health Service grant appeals procedure.
45 CFR Part 16—Department grant appeals process.
45 CFR Part 74—Administration of grants.
45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services—effecutation of Title VI of the Civil Rights Act of 1964.
45 CFR Part 81—Practice and procedure for hearings under Part 80.
45 CFR Part 84—Nondiscrimination on the basis of handicap in federally assisted programs.
45 CFR Part 90—Nondiscrimination on the basis of age in programs or activities receiving Federal financial assistance from HHS.

(b) Several other HHS regulations apply to loans and loan guarantees under this Part. These include, but are not limited to:

45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services—effectuation of Title VI of the Civil Rights Act of 1964.
45 CFR Part 81—Practice and procedure for hearings under Part 80.
45 CFR Part 84—Nondiscrimination on the basis of handicap in federally assisted programs.
45 CFR Part 90—Nondiscrimination on the basis of age in programs or activities receiving Federal financial assistance from HHS.

(6) A new § 110.208 is added as follows:

### § 110.208 For what purposes may grant funds be used?

A grantee may spend funds it receives under this Part only according to the approved application and budget, Title XIII of the Act, the terms and conditions of the grant award, the applicable cost principles specified in Subpart Q of 45 CFR Part 74, and the regulations of this Part.

(7) Section 110.210 is renumbered to § 110.209 and is revised to read as follows:

### § 110.209 What is the effect of a grantee's failure to become or to remain a qualified HMO?

The failure of a grantee to become a qualified HMO in accordance with Subpart F of this Part, or to remain a qualified HMO, is a material failure to comply with the terms of the grant. Upon this failure, the subsequent use and disposition of any property acquired with grant funds will be governed by 45 CFR Part 74.

(a) If the grant project period has not yet expired, this failure is grounds for termination of the grant under 45 CFR Part 74.115(a).

(b) If the grant period has expired, property acquired with grant funds will be deemed, under 45 CFR Part 74, Subpart O, to be no longer needed for the program or project for which it was acquired.

(8) Section 110.211 is renumbered § 110.210 and is revised to read as follows:

### § 110.210 What obligation does the Federal Government have to continue support for an approved project?

(a) The notice of award specifies how long the Secretary intends to support the project without requiring the project to recompete for funds. For feasibility grants under Subpart C and planning grants and loan guarantees under Subpart D, this period, called the project period, will usually be for, and cannot exceed, one year. For initial development grants and loan guarantees under Subpart D, the project period will usually be for 1–3 years and cannot exceed three years.

(b) Generally, the initial development grant or loan guarantee will be for one year initially and subsequent continuation awards will also generally be for one year at a time. Although the project period for a feasibility grant and for a planning grant or loan guarantee is limited to one year, the Secretary may either make one additional grant or loan guarantee for such a project or permit additional time (up to one year) for completion of the project. A grantee or a recipient of a loan guarantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the assistance level of such awards will be made after consideration of such factors as the progress and management practices of the grantee or recipient of the loan guarantee, and the availability of funds. In all cases, continuation awards require a determination by the Secretary that continued assistance is in the best interest of the Federal government.

(c) Neither the approval of any application nor the making of an award commits or obligates the Federal government in any way to make an additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

### § 110.212 [Renumbered as § 110.211]

(9) Section 110.212 is renumbered as § 110.211.

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its providers to assure that the HMO or the health professional coordinating the member's overall health care is kept informed about the services provided to its members by referral resources.

### § 110.109 Special requirements: Titles XVIII and XIX of the Social Security Act.

(a) As provided in section 1307(d) of the Act, an HMO which otherwise complies with section 1301(b) and section 1301(c) of the Act, and with the applicable regulations of this subpart, and which enrolls members who are entitled to insurance benefits under Title XVIII of the Social Security Act or to medical assistance under a State plan approved under Title XIX of that Act, may still be considered as an HMO, if with respect to its Title XVIII and Title XIX members it provides services and is operated as required by Title XVIII or XIX, as appropriate, and regulations thereunder.

(b) Notwithstanding any inconsistent requirements of this subpart, an HMO which enters into a contract with the Secretary under Title XVIII of the Social Security Act or with a State under Title XIX of that Act shall, with respect to its members entitled to insurance benefits or medical assistance under those titles, comply with the applicable Title XVIII or Title XIX requirements, including deductible and coinsurance requirements, enrollment mix and enrollment practice requirements, in accordance with the provisions of Title XVIII or the Title XIX State plan of the State with which it is contracting. Copayment options which are not in accordance with the Title XIX State plan may not be imposed on Title XIX enrollees.

(c) Any grievance procedures authorized under Title XVIII or Title XIX of the Social Security Act are not superseded by the provisions of § 110.108(i).

### § 110.110 Special requirements: Federal Employee Health Benefits Program.

An entity which provides health services to a defined population on a prepaid basis and which has members who are enrolled under the health benefits program authorized by chapter 89 of Title 5, United State Code, may be considered as an HMO for purposes of receiving assistance under this Part if with respect to its other members it (a) provides health services in accordance with section 1301(b) of the Act and the applicable regulations of this Part and (b) is organized and operated in the manner prescribed by section 1301(c) of the Act and the applicable regulations of this Part.

## Subpart B—Federal Financial Assistance: General

AUTHORITY: Sec. 215, 58 Stat. 690, (42 U.S.C. 216); secs. 1301-1318, as amended, 92 Stat. 2131-2141 (42 U.S.C. 300e-300e-17).

SOURCE: 44 FR 42076, July 18, 1979, unless otherwise noted.

### § 110.201 To whom do these regulations apply?

The regulations of this subpart apply to the award of grants, loans, and loan guarantees to public or private entities for projects as authorized by sections 1303, 1304, 1305, and 1305A of the Act.

### § 110.202 Definitions.

"Expansion of services" means (1) the addition of any health service not previously provided by or through the HMO, which requires an increase in the facilities, equipment, or health professionals of the HMO, or (2) the improvement or upgrading of existing facilities or equipment, or an increase in the number or categories of health professionals, of the HMO so that the HMO may provide directly services which it previously provided through contract or referral or which it could not previously provide with its existing facilities or equipment.

"Health system agency" means an entity which has been designated in accordance with section 1515 of the Public Health Service Act; and the term "State Health planning and development agency" means an agency which has been designated in accordance with section 1521 of the Act.

"Nonprofit" as applied to a private entity, agency, institution, or organization means a private entity, agency, institution, or organization, no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

"Significant expansion" means (1) a planned substantial increase in membership of the HMO which will require an increase in the number of health professionals serving members of the HMO or an expansion of the physical capacity of the HMO's total health facilities; or (2) a planned expansion of the service area beyond the current service area which would be made possible by the addition of health service delivery facilities and health professionals to serve members at a new site or sites in areas previously without service sites. Only organizations which have been found by the Secretary to be qualified HMOs are eligible to apply for assistance for expansion under sections 1303 and 1304 of the Act.

### § 110.203 What are the requirements for an application?

(a) *Financial information.* In addition to complying with requirements set forth in the appropriate forms for applying for financial assistance under this part, applicants must submit an audited full financial statement unless exempted by the Secretary. Except for an application under section 1303 of the Act, an applicant whose financial statement shows unobligated cash assets which presumably could be used to conduct all or part of the project or undertaking for which application is made must also submit a detailed statement satisfactory to the Secretary stating why the unobligated cash assets of the applicant are not available or are inadequate for the planned project. (The only assets of the applicant which need be considered in this regard are assets other than those to be used to meet the applicant's contribution requirements and other than those the obligation of which for the project the Secretary determines would jeopardize the applicant's fiscal soundness.) An applicant for a loan or loan guarantee shall also submit a written verification from at least two public or private lending agencies or institutions demonstrating that, after a formal request—

(1) Funds have been denied in the amount requested in the application; or

(2) Funds in the amount requested in the application are available only at an interest rate in excess of those currently in effect for the loan or loan guarantee program, as appropriate, on the date of the application. On the basis of the information submitted, the Secretary will determine whether the applicant would not be able to complete the project or undertaking for which the application is submitted without the assistance applied for.

(b) *Assurances.* Each application must contain the following assurances, as appropriate, which are binding on successors, assignees, and transferees of the applicant, as well as the applicant:

(1) In the case of an application for assistance under section 1303 of the Act, if the survey or other activity supported demonstrates that the development and operation or the expansion of the operation of an HMO is feasible, the applicant will be, or will form, or expand the operation of, as appropriate, and HMO;

(2) In the case of an application for assistance under section 1304 of the Act, the applicant will develop and operate or expand the operation of, as the case may be, an HMO;

(3) When operational as an HMO, the applicant will (i) provide basic health services to its members, (ii) provide these services in the manner prescribed by section 1301(b) of the Act and by the regulations of this part, and (iii) be organized and operated in the manner prescribed by section 1301(c) of the Act and by the regulations of this part;

(4) When operational as an HMO, the applicant will enroll, and maintain an enrollment of, the maximum number of members that is available and potential resources will enable it to serve effectively. Maximum number of members is defined as the actual or projected enrollment which the HMO can serve, considering the availability of the required health manpower in the area to be served by the organization and the capacity of the facilities of the organization;

(5) A statement of intent (including evidence of the applicant's ability) to meet the requirements of paragraphs (1) and (2) of section 1301(b) of the Act and the applicable regulations of this part respecting the fixing of payments for basic health services and supplemental health services for which the member has contracted on a prepayment basis under a community rating system; and

(6) In the case of an application for assistance under sections 1304 and 1305 of the Act filed by a nonprofit entity, the applicant will become a nonprofit HMO, will maintain its nonprofit status unless for good cause shown the Secretary releases the applicant from this assurance, and will upon a change in its nonprofit status notify the Secretary immediately.

(c) *Nonmetropolitan areas.* Each application which evidences or projects an enrollment of at least 66 percent from a nonmetropolitan area shall identify the area and indicate the percent of anticipated enrollment to be drawn from that area.

(d) *Medically underserved areas.* Each application which evidences or projects an enrollment of at least 30 percent of its members from a medically underserved population when the HMO first receives financial assistance or becomes operational shall identify the area in which that population resides, the total population of that area, and the percent of anticipated enrollment to be drawn from the medically underserved area. Medically underserved areas are designated by the Secretary taking into consideration at least the following factors:

(1) Ratio of primary care physicians to population;

(2) Infant mortality rate;

(3) Percentage of the population which is age 65 or over; and

(4) Percentage of the population with family income below the poverty level.

The Secretary will designate these areas only after consideration of the comments, if any, of the appropriate health systems agency or State health planning and development agency whose plan covers any part of the area in which the population group resides.[1]

(e) *Health planning agency reviews.* Each applicant must show in its application that it has sent to each health systems agency whose health service area covers any part of the area to be served by the HMO for which the application is submitted (or if there is no such agency, the State health planning and development agency whose State includes any part of the area to be served) a copy of the application concurrent with its submission to the appropriate Regional Office of the Department of Health, Education, and Welfare. The agency may then review and comment on the application in accordance with § 110.204.

(f) *Health planning agency approvals.* If applicable State law provides that the application may not be submitted without the approval of the health systems agency, or State health planning and development agency, the applicant shall obtain this approval which must be included as a part of the application.

(g) *Other projects under the Public Health Service Act.* The application shall provide written information describing the applicant's development and operation of any prior projects which were supported by grants or by loans or loan guarantees under Title XIII of the Act. Applicants must also describe projects for the planning or operation of health service delivery programs supported under any other titles of the Public Health Service Act, or for which applications under the Act are currently under consideration.

(h) *Other applications under Title XIII of the Act.* Applicants for more than one grant, loan, or loan guarantee under Title XIII of the Act, simultaneously or over the course of time, are not required to submit duplicate information, but shall indicate where the information was previously contained and shall update appropriate information with each subsequent application. Upon receiving a written request, the HMO shall submit to the appropriate planning agency referred to in paragragph (e) any previous applications for grants, loans, or loan quarantees under Title XIII of the Act not already submitted to that agency.

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[1] A list of medically underserved areas already designated may be obtained by writing the Regional Health Administrator in the appropriate Regional Office of the Department of Health, Education, and Welfare at the addresses set forth at 45 CFR 5.31(b).

### § 110.204 What are the standards and procedures for review and comment by the appropriate health systems agency or State health planning and development agency?

(a) *Time, manner, and considerations for review and comment.* If the appropriate health systems agency or State health planning and development agency elects to review and comment upon the application, it shall within 67 days after receiving an application for financial assistance under this part provide to the Secretary, through the appropriate Department of Health, Education, and Welfare Regional Office, comments and recommendations regarding the application. Except as provided in paragraph (c) of this section, the agency shall base its review and comment solely on the following considerations:

(1) The needs of enrolled members and reasonably anticipated new members of the HMO or proposed HMO applying for assistance for the health services proposed to be provided by the organization.

(2) The availability of the proposed health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO or proposed HMO applying for assistance. In assessing the availability of health services from these providers, the agency shall consider only whether the services from these providers:

(i) Would be available under a contract of at least five years duration;

(ii) Would be available and conveniently accessible through physicians and other health professionals associated with the HMO or proposed HMO (for example: Whether physicians associated with the HMO have or will have full staff privileges at a non-HMO hospital);

(iii) Would cost no more than if the services were provided by the HMO or proposed HMO; and

(iv) Would be available in a manner which is administratively feasible to the HMO or proposed HMO.

(b) *Inappropriate considerations for review and comment.*

(1) The health systems agency or State health planning and development agency should not recommend against approval of an application solely because there is an HMO of the same type, as specified in section 1310(b) of the Act, in the same area, or solely because the services being reviewed are not discussed in the applicable health systems plan, annual implementation plan, State health plan, or State medical facilities plan.

(2) The health systems agency or State health planning and development agency should not recommend against approval of an application for financial assistance for planning or initial development or initial operating costs under subparts D and E of this part, which is consistent with the basic objectives, time schedules, and plans of an application which it previously approved or recommended for approval.

(c) *Additional considerations for review and comment.* A health systems agency or State health planning and development agency may propose to the Secretary that it be permitted to base its reviews and comments on additional considerations not set forth in paragraph (a) of this section. Any agency making such a request for permission to use additional considerations shall do so in writing, specifying the reasons for the proposal, and shall send a copy of the request to any applicants for financial assistance under this part whose applications are then being reviewed by the agency. No pending reviews may be delayed because the agency has submitted such a request to the Secretary. The Secretary will approve the request if he finds the additional considerations to be consistent with the purpose of Title XIII of the Act. Unless the Secretary has approved the use of the additional considerations, the agency shall base its reviews and comments solely on the considerations set forth in paragraph (a) of this section.

### § 110.205 What records must be maintained and what reports must be submitted?

(a) Each grant, loan, or loan guarantee awarded under this part is subject to the condition that the recipient shall maintain records which disclose the amount and disposition of the proceeds of the grant, or loan (directly made or guaranteed), the total cost of the undertaking in connection with which the assistance was given or used, the amount of that portion of the cost of the undertaking supplied by other sources, and any other records which will facilitate an effective audit.

(b) The recipient of a grant, loan, or loan guarantee under Title XIII of the Act shall submit a report to the Secretary not later than 90 days after the termination date of each project, describing existing and anticipated plans, developments and operations in accordance with information required under section 1306(b)(3) of the Act.

(c) The recipient shall submit any other reports which the Secretary may require to meet the provisions of the Act and these regulations.

### § 110.206 What additional conditions may the Secretary impose?

The Secretary may, with respect to the approval of any grant, contract, loan, or loan guarantee, impose additional conditions prior to or at the time of any approval when, in his judgment, these conditions are necessary to assure or protect the advancement of the approved project, the interests of public health, or the conservation of project funds.

### § 110.207 What are the government's rights with respect to data developed during the term of Federal financial assistance?

(a) Except for information which is confidential under § 110.208, the government may use, duplicate, or disclose in any manner and for any purpose whatsoever, and have or permit others to do so, all data developed during the term of Federal financial assistance.

(b) Whenever the recipient of assistance under this part will obtain any data from a contractor or subcontractor under a project assisted under this part, it shall include the provisions of this section, of § 110.208, and of 45 CFR § 74.145 (a), (b), and (c) in the contract or subcontract without alteration, making them applicable to the subject matter of the contract or subcontract, and no other clause shall be used to diminish the government's right in that contractor's or subcontractor's data.

(c) As used in this section, the term "data" means writings, films, sound recordings, pictorial reproductions, drawings, designs or other graphic representations, procedural manuals, forms, diagrams, work-flow charts, equipment descriptions, data files and data processing or computer programs, and works of any similar nature (whether or not copyrighted or copyrightable) which are developed during the term of Federal financial assistance.

### § 110.208 What confidentiality requirements apply?

(a) Except as set forth in paragraph (b) of this section, each recipient of assistance under this part shall hold confidential all information obtained by its personnel about participants in the project related to their examination, care, and treatment and shall not divulge it without the individual's authorization, unless it is required by law or is necessary to provided service to the individual or in compelling circumstances to protect the health or safety of an individual.

(b) Information may be disclosed in summary, statistical, or other form which does not identify particular individuals. Information may be disclosed, whether or not authorized by the participants, to the Secretary or the Comptroller General if it is necessary for the performance of their duties under the Act. Records pertaining to project participants may be disclosed, whether or not authorized by the participants, to qualified personnel for the purpose of conducting scientific research, but these personnel may not identify, directly or indirectly, any individual participant in any report of the research or otherwise disclose participant identities in any manner.

(c) Separate HEW regulations at 42 CFR Part 2, set forth standards for maintaining the confidentiality of alcohol and drug abuse patient records. Under § 2.12 of the regulations, the applicability of these requirements extends, for example, to all HMOs which have received a loan from the Secretary under Section 1305 of the Act or which have been granted a tax exempt status by the United States Internal Revenue Service. To the extent that an HMO subject to Part 2 would be authorized under paragraph (b) of this section to make a disclosure prohibited by Part 2, the provisions of Part 2 would control.

### § 110.209 What other HEW regulations apply?

(a) The following HEW regulations also apply to grants under this part:

45 CFR Part 16 Department grant appeals process.

45 CFR Part 74 Administration of grants.

45 CFR Part 80 Nondiscrimination under programs receiving Federal assistance through the Department of Health, Education, and Welfare—Effectuation of Title VI of the Civil Rights Act of 1964.

45 CFR Part 84 Nondiscrimination on the basis of handicap in Federally assisted programs.

(b) The following HEW regulations also apply to loans and loan guarantees made under this subpart:

45 CFR Part 80 Nondiscrimination under programs receiving Federal assistance through the Department of Health, Education, and Welfare—Effectuation of Title VI of the Civil Rights Act of 1964.

45 CFR Part 84 Nondiscrimination on the basis of handicap in Federally assisted programs.

### § 110.210 For what are grantees accountable?

If a grantee under this part fails to become a qualified HMO in accordance with Subpart F of this Part, or fails to remain a qualified HMO, the grantee shall be accountable to the Secretary for all unexpended grant funds and for the then value of all items of real or nonexpendable personal property purchased with grant funds, in addition to all other amounts due under 45 CFR Part 74. This total sum constitutes a debt owed by the grantee to the Federal Government, and the Government may recover it from the grantee or its successors or assignees by setoff or other action as provided by law.

### § 110.211 What obligation does the United States have to continue support for an approved project?

Neither the approval of any project nor any award of financial assistance commits or obligates the United States to make any additional, supplemental, continuation, or other award with respect to any approved project or portion thereof. For continuation support, applicants must make separate applications as the Secretary may direct.

### § 110.212 What is the effect of a grantee's change from non-profit to for-profit status?

(a) Any non-profit private entity which received a grant under section 1304 of the Act and which becomes a for-profit private entity, shall notify the Secretary of this change of status within 30 days of the change.

(b) Unless the Secretary determines, for good cause shown, that repayment would not be in the interests of the United States, any grantee which becomes a for-profit private entity after receiving a grant under section 1304 of the Act, as a non-profit private entity, shall immediately upon this change in status notify the Secretary and repay to the Secretary upon demand the total amount of grant funds received under section 1304. This sum constitutes a debt owed by the grantee to the Federal Government, and the Government may recover it from the grantee or its successors or assignees by setoff or other action as provided by law.

## Subpart C—Grants for Feasibility

SOURCE: 43 FR 6021, Feb. 10, 1978, unless otherwise noted.

### § 110.301 Applicability.

The regulations of this subpart, in addition to the regulations of Subpart B of this part, are applicable to grants awarded pursuant to section 1303 of the Act for projects to conduct surveys or other activities to determine the feasibility of developing and operating or expanding the operation of health maintenance organizations.

### § 110.302 Eligibility.

(a) *Eligible applicants.* Any public or private nonprofit entity which is or proposes to develop or become a health maintenance organization is eligible to apply for an award under this subpart, except that in the case of applications for support of expansion, only organizations which have been found by the Secretary to be qualified health maintenance organizations are eligible to apply.

(b) *Eligible projects.* Awards may be made pursuant to section 1303 of the Act, the regulations of Subpart B of this part, and this subpart, to eligible applicants to assist in conducting surveys or other activities to determine the feasibility of developing or expanding the operation of organizations which meet or propose to meet the requirements under subpart A of these regulations.

### § 110.303 Project elements.

An approvable application must provide:

(a) Statements which describe concisely:

(1) The goals and objectives of the applicant organization and of the proposed health maintenance organization if the proposed health maintenance organization is different from the applicant organization; if it is different, describe the relationship between the two organizations;

(2) The administrative, managerial, and organizational arrangements;

(3) The resources to be used, including consultants whose tasks must be defined adequately to permit an evaluation of the need for such consultants;

(4) The existing or proposed composition of the Board of Directors of the applicant organization and its duties;

(5) The proposed service area and the surrounding community, the number of employed persons and number of primary care physicians located in the proposed service area; and

(6) Intended financial participation of the applicant, specifying the type of contribution, such as cash or services, loan of full- or part-time staff, equipment, space, materials, or other contributions.

(b) In the case of a proposed staff or medical group health maintenance organization, letters from at least three physicians expressing their interest in the health maintenance organization feasibility study in connection with their eventual participation in the health maintenance organization as providers of basic health services.

(c) In the case of a proposed individual practice association health maintenance organization, letters from the local medical society or societies, or from at least three individual physicians, expressing their interest in the health maintenance organization feasibility study in connection with their eventual participation in the health maintenance organization as providers of basic health services.

(d) Evidence that there is interest in the possible development of a health maintenance organization from one or more employers, or unions, or community leaders in the proposed service area.

(e) Plans for conducting the feasibility study which must include a consolidated time-phased milestone chart indicating proposed funding and manpower to be allocated to each of the six activities below, and a narrative explanation of work plans to accomplish the six activities:

(1) Identification of pertinent State laws, regulations, and practices relating to the intended organizational structure and operation as a health maintenance organization;

(2) Identification of major groups or other potential sources of enrollement to which marketing efforts will be directed, including their existing health plan benefits and payments and the level and scope of major health plan benefits and premiums in the community;

(3) Identification of potential providers and available health manpower necessary to provide basic health services to the number of enrollees projected to be served, and provision of evidence of their willingness to partici-

pate in the proposed health maintenance organization;

(4) Development of detailed estimates of expected utilization and the amount to be charged for basic health services when the proposed health maintenance organization becomes operational;

(5) Development of detailed estimates of the enrollment and funds required to reach the financial break-even point. These estimates must take into account all potential sources of income; and

(6) Development of preliminary estimates of the type and number of facilities, if any, necessary to provide health services when the health maintenance organization becomes operational.

(f) In addition, in the case of an operational prepaid health plan which proposes to become a qualified health maintenance organization, an identification of gaps between its current operation and the requirements of subpart A of this Part.

(g) In addition, in the case of a qualified health maintenance organization requesting assistance for significant expansion:

(1) Data on prepaid membership totals for annual intervals over the past five years, or if the health maintenance organizations has not been operating for five years, such data on a quarterly basis for the time during which it has been in operation;

(2) A description of the current health service delivery facilities, including an estimate of their capacity;

(3) The number and specialties of current health professionals serving its members; and

(4) The plans for the proposed significant expansion which demonstrate that the definition of significant expansion in § 110.202(c) will be met.

(h) An assurance that the applicant will cooperate with the appropriate health systems agency and State health planning and development agency; and

(i) Written evidence of notification to the local medical society or societies of the applicant's intention to apply for assistance.

### § 110.304 Evaluation and award.

(a) Within the limits of funds available for such purpose, the Secretary may make awards to cover up to 90 percent of the cost of projects, or in the case of projects which will draw not less than 30 percent, not more than the appropriate percentage (as determined under § 110.108(c)), of their anticipated enrollment from medically underserved populations, up to 100 percent of the costs, to those applicants whose projects will, in his judgment, best promote the purposes of section 1303 of the Act and the regulations of this subpart, taking into account:

(1) The appropriateness and completeness with which the applicant addresses the project elements set forth above;

(2) The comments of the appropriate health systems agency or State health planning and development agency;

(3) The degree to which the goals and objectives of the proposed project will promote the purposes of the Act and are consistent with the generally recognized capability of effectively organized and managed health maintenance organizations to reduce inappropriate hospital utilization, to contain health care costs, to use effectively medical and other health manpower, to emphasize early detection and treatment of illness, and to contribute to a better distribution and quality of health care;

(4) Satisfactory evidence of understanding and commitment to the development of a qualified health maintenance organization on the part of the sponsors and the board of directors of the proposed project;

(5) The qualifications of the project director or proposed project director or other person responsible for completion of the feasibility study and a position description adequate to assure that a well-qualified person has been or will be selected;

(6) The thoroughness of the milestone chart and narrative plan for conducting the feasibility study by project staff and any proposed consultants;

(7) The indications of interest obtained from physicians with respect to

their eventual participation as providers of basic health services;

(8) The probability of financial viability based on potential sources of financial support for development and operations, on potential sources of enrollment, and on the effect of competing health insurance plans;

(9) The inclusion of medically underserved populations in the projected enrollment;

(10) The location and the number of prepaid health plans already providing health services to a defined population in the applicant's proposed service area and to the extent known the number of organizations already studying health maintenance organization development in the proposed service area;

(11) The level of the applicant's intended contribution to the project;

(12) In the case of an existing prepaid health plan, the potential to become a qualified health maintenance organization;

(13) In the case of expansion projects, the potential rate of increase of expansion, or the potential increase in the area to be served by the expanded health maintenance organization.

(b) In considering applications under this subpart, the Secretary will give priority to applications which contain assurances satisfactory to the Secretary that when the organizations become operational not less than 30 percent of their members will be members of a medically underserved population.

### § 110.305 Funding duration and limitation.

(a) The amount of any award shall be determined by the Secretary on the basis of his estimate of the sum necessary for project costs: *Provided, however,* That any single grant may not exceed $75,000.

(b) Feasibility survey applicants may propose that the award period be 12 months or less. Feasibility survey projects shall be completed within the period of the award. The Secretary may make not more than one additional grant for a project for a feasibility survey for which a grant has previously been made, and may permit additional time (up to 12 months) for completion of the project if he determines that the additional grant or additional time, or both, is needed to complete the project adequately.

(c) Funds under grants for feasibility surveys shall be used only for activities set forth in § 110.303(e) and for activities designed to fill the gaps referred to in § 110.303(f).

## Subpart D—Grants and Loan Guarantees for Planning and Initial Development Costs

SOURCE: 43 FR 6023, Feb. 10, 1978, unless otherwise noted.

### § 110.401 Applicability.

The regulations of this subpart, in addition to the regulations to Subpart B of this part, are applicable to:

(a) Grants awarded pursuant to section 1304 of the Act for projects for planning, and initial development of health maintenance organizations or for significant expansion, as defined in § 110.202(c), of the membership of, or areas served, by qualified health maintenance organizations, and

(b) Guarantees made to non-Federal lenders of payment of the principal of and the interest on loans made to—

(1) Nonprofit private entities for such projects for the establishment or expansion of health maintenance organizations, or

(2) Private entities (other than nonprofit private entities) for such projects for health maintenance organizations which will serve medically underserved populations.

### § 110.402 Eligibility.

(a) *Eligible applicants.* (1) Any public entity which is or which proposes to become a health maintenance organization is eligible to apply for a grant under this subpart, except that in the case of applications for support of expansion, only organizations which have been found by the Secretary to be qualified health maintenance organizations are eligible to apply.

(2) Any nonprofit private entity which is or which proposes to become a health maintenance organization is eligible to apply for a grant or a loan guarantee under this subpart, except

that in the case of applications for support of expansion, only organizations which have been found by the Secretary to be qualified health maintenance organizations are eligible to apply.

(3) Any private entity (other than a nonprofit private entity) which is or which proposes to become a health maintenance organization and which proposes to serve a medically underserved population is eligible to apply for a loan guarantee under this subpart, except that in the case of applications for support of expansion, only organizations which have been found by the Secretary to be qualified health maintenance organizations are eligible to apply.

(b) *Eligible projects*—(1) *Grants.* Awards of grants may be made pursuant to section 1304 of the Act and the regulations of Subpart B of this part and this subpart to eligible applicants for planning for the establishment of health maintenance organizations, or for the significant expansion of the membership of, or areas served by the health maintenance organizations meeting the requirements of Subpart A of this part, or for the initial development or significant expansion of such organizations;

(2) *Loan guarantees.* (i) In the case of nonprofit private entities, guarantees may be made pursuant to section 1304 of the Act and the regulations of Subpart B of this part and this subpart to eligible applicants for the payment of the principal of and the interest on loans for planning projects for the establishment of health maintenance organizations, or the significant expansion of existing organizations which have been found by the Secretary to meet the applicable requirements of Title XIII of the Act and the applicable regulations of this part, or for the initial development or significant expansion of such health maintenance organizations.

(ii) In the case of private entities (other than nonprofit private entities), guarantees may be made pursuant to section 1304 of the Act and the regulations of Subpart B of this part and this subpart to eligible applicants. The guarantees shall be for the payment of the principal of and the interest on loans for planning or initial development projects for (A) the establishment of health maintenance organizations, or (B) the significant expansion of health maintenance organizations. For any of these projects, at least 10 percent of the projected members of the health maintenance organization must be from medically underserved populations.

[43 FR 6023, Feb. 10, 1978, as amended at 43 FR 50183, Oct. 27, 1978]

### § 110.403 Project elements for planning.

An approvable application must provide:

(a) Statements which describe in detail:

(1) The goals and objectives of the proposed health maintenance organization;

(2) The administrative, managerial, and organizational arrangements;

(3) The resources to be used including consultants whose tasks must be defined adequately to permit an evaluation of the need for such consultants;

(4) The existing or proposed composition of the Board of Directors of the applicant organization and its duties;

(5) The proposed service area and the surrounding community, the number of employed persons and number of primary care physicians located in the proposed service area; and

(6) The intended financial participation of the applicant, specifying the type of contribution such as cash or services, loans of full- or part-time staff, equipment, space, materials, facilities, or other contributions.

(b) An assurance that the applicant will cooperate with the appropriate health systems agency and State health planning and development agency.

(c) Written evidence of notification to the local medical society or societies of the applicant's intention to apply for assistance.

(d) Evidence that there is support for the project by organizations, or institutions, or employer groups which may participate in the development of the proposed health maintenance organization.

(e) A detailed report of the results of the activities performed during the feasibility survey or study which established the feasibility of developing the health maintenance organization, as well as of any other activities relating to the development of the health maintenance organization undertaken prior to application for planning assistance. With regard to the report of the feasibility survey, information on the following must be included:

(1) Status of the applicant in terms of pertinent State laws, regulations, and practices relating to operating as a health maintenance organization;

(2) Organizational structure of the proposed health maintenance organization;

(3) The types of population groups which would be sources of prepayment for an operational health maintenance organization and other potential sources of payment for services when operational;

(4) Providers of basic health services who have agreed or might reasonably be expected to agree to provide health benefits;

(5) Sources of payment and operational support including:

(i) Preliminary estimate of the amount to be charged for basic health benefits when the proposed health maintenance organization becomes operational; and

(ii) Estimate of enrollment and income required to reach the financial breakeven point; and

(6) A preliminary estimate of facilities required for operational status.

(f) Concise plans for accomplishing planning stage activities, which must include at a minimum, a description of tasks for each activity listed below, accompanied by a time-phased milestone chart indicating proposed funding and manpower to be allocated to each such activity (where circumstances indicate that it would be appropriate and consistent with the intent of the Act, additional activities may be proposed):

(1) Recruitment of key project staff which shall include the employment of a full-time project director;

(2) Planning for, and when appropriate, initiation of action relating to compliance with all applicable State requirements, including State certificate of need programs, and with section 1513(e) of the Public Health Service Act;

(3) Development of formal organization;

(4) Establishment and documentation of community support;

(5) Development of a marketing plan which must include the following:

(i) Market assessment:

(A) Precise description of the service area;

(B) Information about prospects for enrollment of groups, including analysis of competing health benefits plans;

(C) Evidence of a willingness on the part of key prospects to offer the health maintenance organization when operational;

(D) An estimate of market potential for a five year period, including a five year enrollment projection.

(ii) Marketing strategy:

(A) Select the major prospects for enrollment;

(B) Develop alternatives to meet the enrollment projections;

(C) Estimate the level and type of marketing effort required to meet the enrollment projection;

(D) Develop a marketing effort and a detailed budget including staffing requirements.

(iii) Marketing materials:

(A) Develop detailed description of specifications for marketing and enrollment literature;

(B) Develop prototype membership materials including membership cards, subscriber agreements, handbooks and certificates, health questionnaires, etc.

(6) Definition of the health services and options, if any to be offered;

(7) Identification of providers of basic health services needed to provide those services to the projected enrollment, and drafting of proposed agreements to negotiate with these providers;

(8) Planning for necessary facilities and equipment and their financing;

(9) Development of premium structure;

(10) Development of budget and financial plan, including alternative plans if enrollment varies significantly from projections;

(11) Obtaining of required health systems agency or agencies and State health planning and development agency determinations; and

(12) Establishment of the individual practice association entity if appropriate to the intended organizational structure when operational as a health maintenance organization.

(g) In addition, in the case of an operational prepaid health plan which proposes to become a qualified health maintenance organization, an identification of gaps between its current operation and the requirements of Subpart A of this part.

(h) In addition, in the case of a qualified health maintenance organization requesting assistance for significant expansion:

(1) Data on prepaid membership totals for annual intervals over the past five years, or if the health maintenance organization has not been operating for five years, such data on a quarterly basis for the time during which it has been in operation;

(2) A description of the current health service delivery facilities, including an estimate of their capacity;

(3) The number and specialties of current health professionals serving its members; and

(4) The plans for the proposed significant expansion which demonstrate that the definition of significant expansion in § 110.202(c) will be met.

### § 110.404 Project elements for initial development.

An approvable application must provide:

(a) Written evidence satisfactory to the Secretary that the feasibility of the establishment and operation or expansion has been established by the applicant and that sufficient planning for the establishment or expansion has been conducted by the applicant. In addition, applicants must provide the information, assurances and evidence required by § 110.403 (a), (b), (c), (d), and (e), and must report all other activities relating to the development of the health maintenance organization undertaken prior to application for initial development assistance.

(b) Detailed plans, which must include, at a minimum, tasks designed to accomplish the activities listed below, accompanied by a time-phased milestone chart indicating proposed funding and manpower to be allocated to each (where circumstances indicate that it would be appropriate and consistent with the intent of the Act, additional activities may be proposed in the application):

(1) Development of a schedule to meet the requirements of Subpart A of this part;

(2) Completion of activities related to resolution of legal issues;

(3) Recruitment and training of personnel essential for operation as a health maintenance organization;

(4) Development of a comprehensive financial plan;

(5) Organization of physician health services;

(6) Organization of other basic health services;

(7) Development of a schedule to construct, lease, renovate or otherwise obtain health maintenance organization facilities;

(8) Organization of ambulatory care facility;

(9) Implementation of a staffing plan that demonstrates compliance with the appropriate 15 or 30 percent limitation on contracts for basic and supplemental health services (see § 110.104(a)), and formalization of contract arrangements;

(10) Further refinement of the projected market to be served by obtaining specific evidence of employer or union willingness to offer the health maintenance organization option on specific dates;

(11) Initiation of enrollment plan; and

(12) Establishment of any working capital or reserves or both as may be required by State authorities.

(c) Evidence from physicians and from one or more hospitals indicating that they intend to become providers of basic health services for the proposed health maintenance organization:

(1) In the case of an individual practice association-type health maintenance organization, there must be such evidence from a number of physicians adequate to serve the proposed enrollment; and

(2) In the case of a non-individual practice association-type health maintenance organization, there must be such evidence from at least three phy-

sicians, indicating that they are willing to be employed by or to contract with the proposed health maintenance organization.

(d) In the case of an applicant which intends to serve Title XIX eligibles or Title XVIII beneficiaries as a part of the planned enrollment, as appropriate:

(1) Evidence that the State Title XIX agency is willing to negotiate a prepaid capitation contract in the form of a letter or other document from the State Title XIX agency; or

(2) Evidence that the applicant is planning to or has entered into a contract under Title XVIII as a health maintenance organization.

(e) In addition, in the case of an operational prepaid health plan which proposes to become a qualified health maintenance organization, an identification of gaps between its current operation and the requirements of Subpart A of this part.

(f) In addition, in the case of qualified health maintenance organizations requesting assistance for significant expansion:

(1) Data on prepaid membership totals for annual intervals over the past five years, or if the health maintenance organization has not been operating for five years, such data on a quarterly basis for the time during which it has been in operation;

(2) A description of the current health service delivery facilities, including an estimate of their capacity;

(3) The number and specialties of current health professionals serving its members; and

(4) The plans for the proposed significant expansion which demonstrate that the definition of significant expansion in § 110.202(c) will be met.

### § 110.405 Funding duration and limitation.

(a) *Planning projects.* (1) The amount of any award shall be determined by the Secretary on the basis of his estimate of the sum necessary for project costs: *Provided,* That any single grant and the amount of principal of any single loan guaranteed under section 1304 of the Act may not exceed $200,000.

(2) In considering applications for grants for planning projects under this subpart, the Secretary will give priority to applications which contain assurances satisfactory to the Secretary that when the organization becomes operational, not less than 30 percent of its members will be members of a medically underserved population. In considering applications for loan guarantees for planning projects under this subpart, the Secretary will give special consideration to applications for projects for health maintenance organizations which will have at least 10 percent of their projected membership from medically underserved populations. Applicants may propose that the award period be for one year or less, as appropriate to the planning activities to be accomplished. Planning projects shall be completed within the period of the award. The Secretary may not make more than one additional grant or loan guarantee for a planning project for which a grant or loan guarantee has previously been made, and may permit additional time (up to 12 months) for completion of the project if he determines that the additional grant or loan guarantee (as the case may be) or additional time, or both, is needed to complete the project adequately.

(3) Funds under grants and loans guaranteed for planning projects shall be used only for the activities set forth in § 110.403(f) and for activities required to fill the gaps referred to in § 110.403(g).

(b) *Initial development projects.* (1) The amount of any award shall be determined by the Secretary on the basis of his estimate of the sums necessary for project costs: *Provided, however,* That the aggregate amount of loan guarantees and grants for any initial development project may not exceed $1,000,000 or, in the case of a project for a health maintenance organization which will provide services to an additional service area or which will provide services in two or more areas which are not contiguous $1,600,000.

(2) Applicants may propose that the award period for initial development activities be one year or less, as appropriate to the initial development activities to be accomplished. Initial devel-

opment projects shall be completed within the period of the award beginning on the first day of the month in which such award was made, and the number of grants made for any initial development project under section 1304 of the Act may not exceed a total of three. A loan guarantee for an initial development project may only be made for a loan (or loans) for initial development costs incurred in a period not to exceed three years.

(3) In considering applications for grants for initial development projects under this subpart, the Secretary will give priority to applications which contain assurances satisfactory to the Secretary that when the organization becomes operational, not less than 30 percent of its members will be members of a medically underserved population. In considering applications for loan guarantees for initial development projects under this subpart, the Secretary will give special consideration to applications for projects for health maintenance organizations which will have at least 10 percent of their projected membership from medically underserved populations.

(4) Funds under grants and loans guaranteed for projects for initial development shall be used only for activities set forth in § 110.104(b) (except that such funds may not be used for the costs of construction or for recruitment of personnel who will not engage in practice principally for the health maintenance organization) and for activities required to fill gaps referred to in § 110.404(e).

### § 110.406 Evaluation and award.

(a) Within the limits of funds available for such purpose, the Secretary may make awards to cover up to 90 percent of the cost of projects, or in the case of projects which will draw not less than 30 percent nor more than the appropriate percentage (as determined under § 110.108(c)) of its anticipated enrollment from medically underserved populations, up to 100 percent of the costs, to those applicants whose projects will, in his judgment, best promote the purposes of section 1304 of the Act and the regulations of this subpart, taking into account:

(1) The degree to which the proposed project satisfactorily provides for the elements set forth in § 110.403 or § 110.404.

(2) The comments of the appropriate health systems agency or State health planning and development agency.

(3) Whether the feasibility of the project has been established, and in the case of initial development applications, whether all required planning activities have been accomplished.

(4) The appropriateness of the goals and objectives of the proposed project.

(5) The effectiveness the proposed organization may reasonably be expected to have in reducing inappropriate hospital utilization, containing health care costs, using medical and other health manpower, emphasizing early detection and treatment of illnesses, and achieving a better distribution and quality of care.

(6) The capability of the applicant to organize and manage the project successfully.

(7) Evidence of the applicant's intended contribution to the project.

(8) Evidence by letters or similar statements of intent from providers expressing a willineness to be employed by or contract with the proposed health maintenance organization for the provision of basic health services and evidence that providers as necessary, will contract with the health maintenance organization other than as members of its staff or through medical groups or individual practice associations.

(9) Evidence, in form of letters, from individuals, groups, or organizations indicating that they support the development and operation of the proposed health maintenance organization.

(10) The results of the Secretary's assessment of marketing capability and the prospects for eventual financial viability as an operational health maintenance organization without continued Federal support.

(11) The inclusion of medically underserved populations in groups to be enrolled.

(12) Location relative to the number of organizations providing health services to a defined population on a pre-

paid capitation basis, which are already operating in the area.

(13) The percentage of anticipated total enrollment to be drawn from nonmetropolitan areas to be served.

(14) In the case of an existing organization operating on a prepaid capitation basis, the applicant's potential for expeditious transition into a qualified health maintenance organization.

(15) In the case of expansion projects, the potential rate of increase of expansion, or the potential increase in the area to be served by the expanded health maintenance organization.

(b) In considering applications under this subpart the Secretary will give priority to applications which contain assurances satisfactory to the Secretary that when the organizations become operational, not less than 30 percent of their members will be members of a medically underserved population.

**§ 110.407 Loan guarantee provisions.**

(a) *Disbursement of loan proceeds.* The principal amount of any loan guaranteed by the Secretary under this subpart shall be disbursed to the applicant in accordance with an agreement to be entered into between the parties to the loan and approved by the Secretary.

(b) *Length and maturity of loans.* The principal amount of each loan guarantee, together with interest thereon, shall be repayable over a period of 22 years, beginning on the date of endorsement of the loan guarantee by the Secretary. The Secretary may however, approve a shorter repayment period where he determines that a repayment period of less than 22 years is more appropriate to an applicant's total financial plan.

(c) *Repayment.* The principal amount of each loan guarantee, together with interest thereon, shall be repayable in accordance with a repayment schedule which is to be agreed upon by the parties to the loan and approved by the Secretary prior to or at the time of his endorsement of the loan. Unless otherwise specifically authorized by the Secretary, each loan guaranteed by the Secretary shall be repayable in substantially level combined installments of principal and interest, to be paid at intervals not less frequently than annually, sufficient to amortize the loan through the final year of the life of the loan. Principal repayment may be deferred, with payment of interest only by the applicant during a period to be specified in an agreement between the applicant and the Secretary.

## Subpart E—Loans and Loan Guarantees for Initial Operating Costs

SOURCE: 43 FR 6026, Feb. 10, 1978, unless otherwise noted.

**§ 110.501 Applicability.**

The regulations of this subpart, in addition to the regulations of Subpart B, of this part are applicable to loans and loan guarantees awarded pursuant to section 1305 of the Act.

**§ 110.502 Definitions.**

(a) "Operating cost" means any cost which under generally accepted accounting principles or under accounting practices prescribed or permitted by State regulatory authority is not a capital cost and which is incurred on or after the first day of the applicable period of operation or expansion as defined in paragraph (b) of this section: *Provided,* That payments made by a health maintenance organization during such applicable period to reduce balance sheet liabilities existing at the beginning of such period are operating costs to the extent that they are expressly approved by the Secretary at the time the loan or loan guarantee is made. In addition, when deposits of funds to restricted reserve accounts are required by State authority, deposits made during such applicable period are operating costs.

(b) "First 60 months of operation or expansion" means the 60-month period beginning on the first day of the month during which the health maintenance organization first provides services to members, or in the case of significant expansion, first provides services in accordance with its expansion plan.

(c) "Any twelve month period" means the twelve month period beginning on the first day of any month.

(Sec. 215, 58 Stat. 690 (42 U.S.C. 216); secs. 1301-1318, as amended, 92 Stat. 2131-2141 (42 U.S.C. 300e—300e-17))

[43 FR 6026, Feb. 10, 1978, as amended at 44 FR 10603, Feb. 22, 1979]

### § 110.503 Eligibility.

(a) *Eligible applicants.* (1) Any public qualified health maintenance organization is eligible to apply for a loan under this subpart.

(2) Any nonprofit private qualified health maintenance organization is eligible to apply for a loan or a loan guarantee under this subpart.

(3) Any private (other than a nonprofit private) qualified health maintenance organization which will serve a medically underserved population is eligible to apply for a loan guarantee under this subpart.

(b) *Eligible projects*—(1) *Loans.* In the case of public or nonprofit private qualified health maintenance organizations, loans may be made pursuant to section 1305 of the Act and the regulations of Subpart B of this part and this subpart to eligible applicants to assist them in meeting the amount by which their operating costs during a period not to exceed the first 60 months of their operation exceed their revenues in such period, or in meeting the amount by which their operating costs, which the Secretary determines are attributable to significant expansion in their membership or area served, as defined in § 110.202(c), and which are incurred during a period not to exceed the first 60 months of their operation after such expansion, exceed their revenues in that period which the Secretary determines are attributable to such expansion.

(2) *Loan guarantees.* Loan guarantees may be made pursuant to section 1305 of the Act, and the regulations of Subpart B of this part and this subpart to guarantee to non-Federal lenders payment of the principal of and the interest on loans made to any nonprofit private qualified health maintenance organization or any private (other than a nonprofit private) qualified health maintenance organization for the amounts referred to in paragraph (b)(1) of this section: *Provided,* That at least 10 percent of the projected members of any such private (other than nonprofit private) qualified health maintenance organization are from a medically underserved population.

### § 110.504 Project elements.

An approvable application must provide:

(a) Statements which describe in detail:

(1) The applicant's adequate accomplishment of feasibility survey, planning, and development activities; and

(2) The health maintenance organization's management capability.

(b) Detailed information on the health maintenance organization's marketing plan and enrollment forecasts and experience.

(c) A detailed narrative statement describing:

(1) All existing and planned provider arrangements including copies of all executed contracts; and

(2) All facilities to be used in the delivery of health services.

(d) Financial information in such detail as the Secretary may prescribe.

(e) Evidence that any certificate of need required under State law for the operation of the health maintenance organization has been obtained by the applicant.

### § 110.505 Reserve requirement.

The applicant receiving a loan or loan guarantee under section 1305 of the Act shall establish a restricted reserve account beginning at the point when the revenues and operating costs of the health maintenance organization reach the break-even point, or by the end of the 60 month period following the making of the loan or the guarantee under section 1305 of the Act, whichever is sooner, unless a longer period is approved by the Secretary. This reserve shall be so constituted as to accumulate no later than twelve (12) years following the endorsement of the loan or loan guarantee, an aggregate amount equal to one year's principal of and interest on the loan, as determined under the terms of the loan made or guaranteed.

### § 110.506 Evaluation and award.

Within the limits of funds available for such purposes, the Secretary may award loans or loan guarantees to those applicants whose projects will, in his judgment, best promote the purposes of section 1305 of the Act and the regulations of this part, taking into account:

(a) The ability of the health maintenance organization to achieve financial viability;

(b) The ability of the health maintenance organization to make repayments of the principal and interest when due and to have additional funds to defray the remaining operating deficits;

(c) The comments, if any, of the appropriate health systems agency or State health planning and development agency;

(d) The relative distribution of qualified applicants with respect to the following factors:

(1) The inclusion of medically underserved populations in the groups to be enrolled;

(2) Location relative to the number of organizations providing health services to a defined population on a prepaid capitation basis, which are already operating in the proposed area; and

(3) The percentage of anticipated total enrollment drawn from nonmetropolitan areas served or to be served by the applicant.

### § 110.507 Funding duration and limitation.

(a) The aggregate amount of principal of loans made or guaranteed, or both, under section 1305 of the Act for a health maintenance organization shall not exceed $2,500,000. In any fiscal year the amount disbursed to a health maintenance organization under section 1305 of the Act and this subpart (either directly by the Secretary or by an escrow agent under the terms of an escrow agreement or by a lender under a loan guaranteed under section 1305 of the Act and this subpart) may not exceed $1,000,000.

(1) The aggregate amount of principal of loans made to an HMO, or guaranteed for an HMO, or both, under section 1305 of the Act, shall not exceed the applicable maximum amounts provided in section 1305.

(2) In any twelve month period, the amount disbursed to an HMO under section 1305 of the Act (either directly by the Secretary or by an escrow agent under the terms of an escrow agreement or by a lender under a loan guaranteed under section 1305 of the Act) may not exceed the maximum amounts provided in section 1305.

(b) The approval of any loan or loan guarantee shall not obligate the United States in any way to make any additional loan or loan guarantee with respect to the approved application or portion thereof, except as may be otherwise set forth in the agreement between the United States and the approved applicant.

(c) In considering applications for loan guarantees under section 1305 of the Act and this subpart, the Secretary will give special consideration to applications for health maintenance organizations which will serve medically underserved populations.

(Sec. 215, 58 Stat. 690 (42 U.S.C. 216); secs. 1301-1318, as amended, 92 Stat. 2131-2141 (42 U.S.C. 300e—300e-17))

[43 FR 6026, Feb. 10, 1978, as amended at 44 FR 10603, Feb. 22, 1979]

### § 110.508 Loan provisions.

(a) *Disbursement of loan proceeds.* The principal amount of any loan made or guaranteed by the Secretary under this subpart shall be disbursed to the applicant in accordance with an agreement to be entered into between the parties to the loan and approved by the Secretary.

(b) *Length and maturity of loans.* The principal amount of each loan or loan guarantee, together with interest thereon, shall be repayable over a period of 22 years, beginning on the date of endorsement of the loan, or loan guarantee by the Secretary. The Secretary may, however, approve a shorter repayment period where he determines that a repayment period of less than 22 years is more appropriate to an applicant's total financial plan.

(c) *Repayment.* The principal amount of each loan or loan guarantee, together with interest thereon, shall be repayable in accordance with a repayment schedule which is to be agreed upon by the parties to the loan or loan guarantee and approved by the

Secretary prior to or at the time of his endorsement of the loan. Unless otherwise specifically authorized by the Secretary, each loan made or guaranteed by the Secretary shall be repayable in substantially level combined installments of principal and interest to be paid at intervals not less frequently than annually, sufficient to amortize the loan through the final year of the life of the loan. Principal repayment during the first 60 months of operation may be deferred, with payment of interest only by the applicant during such period.

## Subpart F—Qualification of Health Maintenance Organizations

SOURCE: 42 FR 29414, June 3, 1977, unless otherwise noted.

### § 110.601 Applicability.

The regulations of this subpart apply to any entity seeking a determination by the Secretary under section 1310(d) of the Act that it is a qualified health maintenance organization. (See § 110.109 concerning the requirements for a health maintenance organization with members who are entitled to insurance benefits under Title XVIII (Medicare) of the Social Security Act or to medical assistance under a State plan approved under Title XIX (Medicaid) of such Act. See § 110.110 concerning the requirements for a health maintenance organization with members who are enrolled under the Federal Employees' Health Benefits Program.)

### § 110.602 Definitions.

In addition to the terms defined in § 110.101, as used in this subpart:

(a) "Operational qualified health maintenance organization" means a health maintenance organization which the Secretary has determined provides basic and supplemental health services to all of its members in accordance with Subpart A of this part and is organized and operated in accordance with Subpart A of this part.

(b) "Transitionally qualified health maintenance organization" means an entity which operates a prepaid health care delivery system and which the Secretary has determined meets the requirements of § 110.603(b). (A transitionally qualified health maintenance organization is deemed a "qualified health maintenance organization" for the purpose of compliance by an employer which has a contract with such health maintenance organization with the requirements of section 1310(a) of the Act so long as the health maintenance organization complies with its time-phased plan approved by the Secretary under § 110.603(b)(2)(iii).)

(c) "Pre-operational qualified health maintenance organization" means an entity which the Secretary has determined will, when it becomes operational as a prepaid health care delivery system, be an operational qualified health maintenance organization.

[42 FR 29414, June 3, 1977; 42 FR 32234, June 24, 1977]

### § 110.603 Requirements for qualification.

Upon the basis of an application submitted in accordance with this subpart and such additional information and investigation (including site visits) as the Secretary may require:

(a) The Secretary will determine that an entity is an operational qualified maintenance organization, if he finds that the entity meets the requirements of Subpart A of this part and if the entity provides written assurances that it:

(1) Provides and will provide basic and supplemental health services to its members;

(2) Provides and will provide such services in the manner prescribed by section 1301(b) of the Act and Subpart A of this part;

(3) Is organized and operated, and will continue to be organized and operated, in the manner prescribed by section 1301(c) of the Act and Subpart A of this part;

(4) Under arrangements which will safeguard the confidentiality of patient information and records, will provide access to the Secretary and the Comptroller General or any of their duly authorized representatives for the purpose of audit, examination or evaluation to any books, documents, papers, and records of the entity relating to its operations as a health main-

tenance organization, and to any facilities operated by the entity; and

(5) Will continue to comply with any other assurances which the entity has given to the Secretary under §§ 110.203(e); 110.303(b); and 110.403(b).

(b) The Secretary may determine that an entity is a transitionally qualified health maintenance organization if the entity currently is organized and currently is providing prepaid health services as described in this paragraph, and provides assurances satisfactory to the Secretary that it will:

(1) With respect to all new group and individual (non-group) contracts which it enters into after the date of the Secretary's determination that the entity is a transitionally qualified health maintenance organization, provide basic and supplemental health services to members enrolled under such contracts and will provide such services in the manner prescribed by Subpart A of this part and will with respect to such members, be organized and operated in accordance with § 110.108.

(2) With respect to its group and nongroup contracts which are in effect on the date of such determination, and which are renewed or renegotiated during the period approved by the Secretary under paragraph (b)(2)(iii) of this section in accordance with the plan so approved:

(i) Provide at least those services specified in the following sections of this part except that these services may be limited as to time and cost: § 110.102(a)(1) (physician services); § 110.102(a)(2) (outpatient services and inpatient hospital services); § 110.102(a)(3) (medically necessary emergency health services); and § 110.102(a)(6) (diagnostic laboratory and diagnostic and therapeutic radiologic services);

(ii) Be organized and operated in accordance with § 110.108 (except that it need not assume full financial risk for the provision of basic health services as required by § 110.108(b), and need not abide by the limitations on insurance of § 110.108(b) (1) and (3)) and provide that payment for basic health services shall be in accordance with § 110.105 (except that it need not comply with the community rating system as required by § 110.105(a)(3), and need not comply with the limitations on copayments of § 110.105(a)(4), and the requirement of § 110.106(b) that supplemental health services payments which are fixed on a prepayment basis be fixed under a community rating system);

(iii) Implement a time-phased plan acceptable to the Secretary which specifies definite steps for meeting, on a contract-by-contract (or category of contracts) basis, within a period not to exceed 3 years from the date of the Secretary's determination of qualification, all the requirements of Subpart A of this part; and

(iv) Upon completion of the time-phased plan:

(A) Provide basic and supplemental health services to all of its members;

(B) Provide such services to all of its members in the manner prescribed by Subpart A of this part; and

(C) Be organized and operated in the manner prescribed by Subpart A of this part.

(3) A health maintenance organization which has more than one regional component, as defined by § 110.101(l)(4), will be considered qualified for those regional components which have signed assurances in accordance with paragraphs (b)(1) and (b)(2) of this section: *Provided*, That all of the regional components have signed such assurances within one year of the date on which the first of the regional components signs these assurances. In the event that not all regional components have signed these assurances within this one year period or if any of them have failed to comply with the time limitation of paragraph (b)(2)(iii) of this section, the qualification of the entire entity will be terminated.

(4) The assurances specified in paragraphs (b)(1) and (b)(2) of this section need not be executed on behalf of the entity until it has been notified that the application is otherwise approvable. At such time, the applicant must specify the date on which such assurances will be made effective and must execute the assurances accordingly. The Secretary's approval of the appli-

cation will be effective on the date so specified.

(c) The Secretary may determine that an entity is a preoperational qualified health maintenance organization if it provides assurances satisfactory to the Secretary that it will become operational within 30 days following the Secretary's determination of qualification, and will, when it becomes operational, meet the requirements of Subpart A of this part. Upon notification by the entity to the Secretary that the entity has become operational, the Secretary will, within 30 days of such notification, make a determination whether the entity is an operational qualified health maintenance organization; in the absence of such a determination the organization is not an operational qualified health maintenance organization even though it becomes operational.

### § 110.604 Application requirements.

(a) An entity seeking a determination that it is a qualified health maintenance organization pursuant to this subpart shall apply to the Secretary at such time and in such form and manner as the Secretary may prescribe.[1] The application must be executed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the statute and the regulations of this part. The application shall provide a complete description of how the entity meets or will meet the requirements of Subpart A of this part and applicable sections of the Act as set forth in a separate form[2] provided by the Secretary.

(b) In addition, each application shall describe interrelationships, if any, between the entity and any of the entity's contractors which provide a professional health service or administrative function or service to the entity. Such description should include identification of interrelationships such as common financial or beneficial ownership, or common directorship or trusteeship. However, descriptions of contracts for nonmedical services are required only if the interrelationship represents, in the aggregate, dollar amounts in excess of 5 percent of either party's income or expenses, whichever is smaller. If no such interrelationships exist, the application shall so state.

### § 110.605 Evaluation and determination of qualification.

(a) The Secretary will evaluate applications submitted under this subpart, and will obtain such additional information as he may require, employing site visits, public hearings or any other procedures determined appropriate by him and will determine whether the applicant meets the appropriate requirements of §§ 110.603 and 110.604, section 1301 of the Act, and Subpart A of this part.

(b) The Secretary will notify each entity applying for qualification under this subpart of his determination and the basis for such determination, and will publish in the FEDERAL REGISTER the names, addresses, and descriptions of the service areas of the newly qualified health maintenance organizations on a monthly basis, and a cumulative list of all qualified health maintenance organizations on an annual basis.

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[1] Applicants should be aware that provisions of the Freedom of Information Act, 5 U.S.C. 552, may require disclosure of certain official Government records. Regulations of the Department of Health, Education, and Welfare, 45 CFR 5.71, provide exceptions to disclosure. Applicants submitting material which they feel is covered by these exceptions should label such material "Privileged" and include a concise explanation of the applicability of 45 CFR 5.71. In the event that the Secretary determines that such material is not appropriately labeled "Privileged" under 45 CFR 5.71, he will inform the applicant of such determination and, if the applicant does not concur, allow the applicant to withdraw his application. Otherwise, the Secretary will not voluntarily disclose such material and will notify the applicant of any court process or subpoena to compel such disclosure.

[2] Application forms and instructions may be obtained by writing the Office of Health Maintenance Organizations Qualification and Compliance, Assistant Secretary for Health, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Maryland 20857 or the Regional Health Administrator in the appropriate Regional Office of the Department of Health, Education, and Welfare at the addresses set forth at 45 CFR 5.31(b).

(c) Copies of lists published pursuant to paragraph (b) of this section may be obtained from, and additional information regarding qualified health maintenance organizations will be available for public inspection between the hours of 8:30 a.m. and 5 p.m., Monday through Friday at the Office of Health Maintenance Organizations Qualification and Compliance, Assistant Secretary for Health, Department of Health, Education, and Welfare, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

(d) Upon the denial of an application for qualification under this subpart, the Secretary will, in writing, so notify the entity making such application and shall provide such entity a reasonable opportunity for a reconsideration of such determination under paragraph (e) of this section or for a fair hearing under paragraph (f) of this section.

(e) A request for reconsideration shall be submitted in writing, within 60 days following the date of the notification of denial, addressed to the officer or employee of the Department of Health, Education, and Welfare who has denied the application, and shall set forth the grounds upon which such reconsideration is requested, specifying the material issues of fact and of law upon which the applicant relies. Reconsideration will be based upon the record compiled during the qualification review proceedings, materials submitted in support of the request for reconsideration, and other relevant materials available to the Secretary. Written notice of the reconsidered determination will be provided to the entity seeking reconsideration. Such notice shall set forth the basis for the determination and shall inform the entity of its rights to seek a fair hearing under paragraph (f) of this section.

(f) Any entity dissatisfied with an initial determination or a reconsidered determination of its application for qualification under this subpart may, within 60 days following the date of notification of any such determination, request a fair hearing. Such request shall be made in writing and shall specify the material issues of fact upon which it is based.

NOTE: Pending promulgation of regulations governing fair hearings, applicants requesting a hearing will be provided a copy of applicable procedures.

## Subpart G—Restrictive State Laws and Practices

### § 110.701 Restrictive laws and practices.

(a) In the case of any entity—

(1) Which cannot do business as a health maintenance organization in a State in which it proposes to furnish basic and supplemental health services because that State by law, regulation, or otherwise—

(i) Requires as a condition to doing business in that State that a medical society approve the furnishing of services by the entity,

(ii) Requires that physicians constitute all or a percentage of its governing body,

(iii) Requires that all physicians or a percentage of physicians in the locale participate or be permitted to participate in the provision of services for the entity, or

(iv) Requires that the entity meet requirements for insurers of health care services doing business in that State respecting initial capitalization and establishment of financial reserves against insolvency, and

(2) For which a grant, contract, loan, or loan guarantee was made under the Act or which is a qualified health maintenance organization for purposes of section 1310 of the Act (relating to employees' health benefits plans), such requirements shall not apply to that entity so as to prevent it from operating as a health maintenance organization in accordance with section 1301 of the Act and these regulations.

(b) No State may establish or enforce any law which prevents a health maintenance organization for which a grant, loan, or loan guarantee was made under the Act or which is a qualified health maintenance organization for purposes of section 1310 of the Act (relating to employees' benefits plans), from soliciting members through advertising its services, charges, or other nonprofessional aspects of its operation. This subsection does not authorize any advertising which identifies, refers to, or makes any qualitative judgment concerning, any health professional who provides services for a health maintenance organization.

## Subpart H—Employees' Health Benefits Plans

SOURCE: 43 FR 17682, Apr. 25, 1978, unless otherwise noted.

### § 110.801 Definitions.

In addition to the terms defined in § 110.101 and § 110.602 of this Part, as used in this subpart:

(a) "Employer" shall have the same meaning as that given such term in Section 3(d) of the Fair Labor Standards Act of 1938, as amended, (29 U.S.C. 203(d), 203(x)), except that the term "employer" does not include (1) the Government of the United States, the government of the District of Columbia or any territory or possession of the United States, a State or any political subdivision thereof, or any agency or instrumentality (including the United States Postal Service and Postal Rate Commission) of any of the foregoing; or (2) a church, convention or association of churches, or any organization operated, supervised or controlled by a church, convention, or association of churches which organization (i) is an organization described in section 501(c)(3) of the Internal Revenue Code of 1954, and (ii) does not discriminate (A) in the employment, compensation, promotion, or termination of employment of any personnel, or (B) in the extension of staff or other privileges to any physician or other health personnel, because such persons seek to obtain or obtained health care, or participate in providing health care, through a health maintenance organization.

(b) "Bargaining representative" means a representative designated or selected for the purposes of collective bargaining under the National Labor Relations Act, as amended, (29 U.S.C. 151 *et seq.*) or under the Railway Labor Act, as amended, (45 U.S.C. 151 *et seq.*) or under a public entity collective bargaining agreement, or under the laws of any State or political subdivision thereof, or other employee representative designated or selected under any law.

(c) "Public entity" means a State as defined at section 2(f) of the Public Health Service Act (42 U.S.C. 201(f)), a political subdivision of a State or any agency or instrumentality of the foregoing. "Political subdivision" includes counties, parishes, townships, cities, municipalities, towns, villages, and incorporated villages.

(d) "Employee" means any individual employed by an employer or public entity whether on a full- or part-time basis.

(e) "Eligible employee" means an employee who meets the terms and conditions established by an employer or public entity or designee, to participate in a health benefits plan.

(f) "Designee" means any person or entity authorized to act on behalf of an employer, a group of employers, or a public entity, to offer the option of membership in a qualified health maintenance organization to the eligible employees of such employer, group of employers, or public entity.

(g) "Service area" means the particular geographic area described by the health maintenacne organization as its service area as part of its application for a determination that it is a qualified health maintenance organization (see § 110.604 of this part), or such other area defined by the health maintenance organization and found by the Secretary to be the area within which basic and supplemental health services are available and accessible to members as required by section 1301(b)(4) of the Act and § 110.107(b) of this part.

(h) "Health benefits" means health benefits and services.

(i) "Health benefits plan" means any arrangement for the provision of, or payment for, any of the basic and supplemental health benefits described in §§ 110.101(b) and (c) of this part offered to eligible employees, or to such employees and their eligible dependents, by or on behalf of an employer or public entity.

(j) "To offer a health benefits plan" means to make participation in a

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Public Health Service

## 42 CFR Part 110

## Health Maintenance Organizations; Employees' Health Benefits Plans

**AGENCY:** Public Health Service, HHS.

**ACTION:** Final Regulations.

**SUMMARY:** This rule amends the Public Health Service regulations by setting forth revised requirements for certain employers, States, and political subdivisions of States to include in any health benefits plans offered to their employees the option of membership in qualified health maintenance organizations (HMOs). These changes are made as a result of public comments received on the notice of proposed rulemaking (NPRM) published on July 18, 1979. Certain minor technical and editorial changes have also been made.

**EFFECTIVE DATE:** This rule is effective on December 1, 1980.

**FOR FURTHER INFORMATION CONTACT:** Howard R. Veit, Director, Office of Health Maintenance Organizations, Park Building—3rd Floor, 12420 Parklawn Drive, Rockville, Maryland 20857, 301/443-4106.

**SUPPLEMENTARY INFORMATION:** On July 18, an NPRM was published in the **Federal Register** (44 FR 42083-91) proposing changes to 42 CFR Part 110, Subpart H, issued under Title XIII of the Public Health Service Act, as amended (the Act). Section 1310 of the Act (42 U.S.C. 300e-9) requires certain employers, States, and political subdivisions of States to include in the health benefits plans offered their employees the option of membership in qualified health maintenance organizations (HMOs).

Interested persons were given an opportunity to submit comments on the proposed amendments by September 17, 1979. Forty-four comments were received by September 17, 1979, and three were received after that date. All comments received were considered in revising these regulations.

As an introductory note, the Department wishes to emphasize that to the extent that the employing entity (the collective term for employers, States and political subdivisions of States) and qualified HMOs can negotiate successfully the inclusion of the HMO option(s) in the employing entity's health benefits plan, it encourages such negotiation. However, in order for an HMO to maintain its status as a qualified HMO, it must provide services and be organized and operated in accordance with Subpart A of this Part ("Requirements for a Health Maintenance Organization"). Thus, in negotiating with a qualified HMO, an employing entity may not insist upon any terms which would require the HMO to violate any Subpart A requirements.

The comments received, responses thereto, and the changes made, if any, are summarized below:

1. Proposed § 110.803(a) defined when the request for inclusion by an HMO must be received by an employing entity in terms of the expiration or renewal date of certain contracts. Subparagraph (2)(ii) of that section stated that a collective bargaining agreement that is "for a fixed term in excess of one year and has provisions for periodically changing wages, hours, or conditions of employment * * *" is to be considered as either expired or renewable at the time provided by the agreement for discussion of these changes. Two commenters suggested that the term "periodically changing" was imprecise in that it covered both those provisions of the contract that changed automatically on a periodic basis without the need for discussion as well as those provisions that provided for a periodic discussion of changes. The Department notes that it intended for this provision to apply only when the contract contained the latter type of provision. It notes further that the section, as proposed, was also inadvertently broader than intended in that it referred to provisions for periodically changing "wages, hours, or conditions of employment." The Department intended that only provisions that provided for renegotiating health benefits should be considered in determining when the HMO should submit its request for inclusion. The Department believes that more precision is necessary in order to clarify both of these points. Accordingly, the phrase "* * * and provides that its terms regarding health benefits may be renegotiated during the term of the agreement * * *" has been substituted in § 110.803(a)(2)(ii) in place of the phrase "has provisions for periodically changing wages, hours, or conditions of employment." The same change has been made in § 110.807(a)(2), which relates to when the offer of the HMO option is to be raised in the collective bargaining process.

2. The purpose of § 110.803(c) is to require the HMO to furnish the employing entity with a broad description of the way the HMO is organized and operated, including sufficient information for it to determine whether it is subject to a request for inclusion by the HMO and, if so, and if there are competing HMOs, to determine which HMO(s) to offer. Section 110.803(c)(4) requires an individual practice association (IPA) type HMO to furnish to the employing entity a list of the IPA members by name, specialty, address, days and hours of operation and whether they are accepting new patients from the HMO membership, with the listing current within 90 days of the HMO's request for inclusion. One commenter requested that the HMO be required to list only the number of physicians in the IPA and another suggested that the HMO should list the telephone numbers of the IPA physicians instead of their days and hours of operation. The Department agrees that the proposed requirement is burdensome on the HMO and that employing entities do not need all of the information it would have required the HMO to provide. The Department believes that a more appropriate way to reduce the burden on the HMO is to delete the requirement that it include the addresses and days and hours of operation of the IPA physicians. Accordingly, § 110.803(c)(4) has been amended to require the HMO to list the IPA members by name, specialty, and whether they are accepting new patients from the HMO membership.

Other commenters noted the information required to be submitted about the IPA, as well as that required to be submitted by the non-IPA type HMOs under § 110.803(c)(5), could be inaccurate or out-of-date at the time of enrollment. The Department thinks that a listing current within 90 days of the HMO's request for inclusion is sufficient to meet the needs of the employing entity when the HMO makes this request. It emphasizes, however, that § 110.108(c) of Subpart A of this Part provides clearly that the HMO has the obligation to disclose fully and fairly information to prospective enrollees at the time of the offer of enrollment, including a general description of participating providers, as well as the locations and hours of service of the HMO.

3. Proposed § 110.803(c)(9) would have required the HMO to provide the employing entity with a report of the financial condition of the HMO consisting of its most current financial statements in addition to its most recently audited annual set of financial statements. One commenter opposed this requirement as being not only burdensome to the HMO, but also

potentially misleading to the employing entity in that the HMO's most current financial statements were not required to be audited. Other commenters suggested that the provision be revised to require the HMO to include a narrative description of its current financial position, as this would be more comprehensible to the layman. The Department agrees that this section should be changed in the interest of minimizing the burden on the HMO while at the same time providing that accurate, relevant information will be available to the employing entity. Accordingly, this section has been revised by deleting the requirement that the HMO must submit its most current financial statements. It now requires the HMO to provide only its most recently audited annual financial statements.

4. Proposed § 110.803(c)(12) would have required an HMO to provide the employing entity its proposed rates for basic and supplemental services to be charged by the HMO on the effective date of the HMO coverage. Under certain conditions, copayment levels and the corresponding premium rates were also required to be stated. A number of commenters requested clarification of this provision. In response to an inquiry as to which rating structures need to be included, the Department notes that, as a minimum, the HMO must provide its rates for an individual and for two or more persons. In response to an inquiry as to when, if ever, an HMO must furnish rates for supplemental health services and copayments, the offering of which are subject to negotiation (see discussion below in section 15), the Department notes that rates for the supplemental health services and copayments yet to be negotiated are not required to be provided to the employing entity at the time of the HMO's request for inclusion.

Additionally, a number of commenters were concerned that the HMO's statement of its proposed rates would be construed by the employing entity as a guarantee by the HMO that these would be its actual rates. These commenters felt that such an interpretation of the provision would be unfair because an HMO, at the time it requests inclusion, may not necessarily know: (a) The day on which the coverage for employees selecting the HMO option will begin; (b) the HMO's own cost experience in the interim before final rates are determined; and (c) the employing entity's preferred rating structure.

The Department notes that it did not intend to require the HMO to submit, at the time of its request, guaranteed rates. It agrees with the commenters that this interpretation of § 110.803(c)(12) would be unreasonable. It also believes that, because of the uncertainties inherent in estimating rates, HMOs should be given the option of stating their current rates (and the dates these rates become effective) instead of their estimated rates. Accordingly, the Department has revised the section. It now requires HMOs to state either (a) their current rates, including copayments, if any, for basic (and uniformly included supplemental) health services and the dates these rates became effective, or (b) their estimated rates for these services.

5. Proposed § 110.803(d) would have required the employing entity to respond, within 30 days of receipt of a request by an HMO for inclusion, with information enabling the HMO to determine whether the employing entity is required to offer the HMO option upon proper request.

The comments received by the Department as to this proposal and its responses thereto are as follows: (a) A number of commenters requested that the proposed 30 day response period be extended to assure that the employing entity had sufficient time to gather the necessary information. The Department agrees that a longer response period would be beneficial and has changed the 30 day response period to 60 days. The Department has extended similarly to 60 days the proposed 30 day period in § 110.803(e), which applies to the length of time the employing entity has to notify the HMO when it has concluded that the HMO's request is inadequate; (b) Two commenters recommended that since an employing entity is not subject to section 1310 of the Act unless 25 or more of its employees reside in the service area of the HMO, such an entity should be required to include information regarding its employees' health benefits plan only if it has 25 or more employees who reside within the service area of the HMO. The Department agrees with this comment and has incorporated this change into the regulation; (c) One commenter requested that, in order to inform the HMO more precisely, the employing entity should include, in addition to its contribution levels, the dates on which they became effective. The Department agrees that this information would be helpful to the HMO in deciding how to proceed with its request for inclusion in the employing entity's health benefits plan and has incorporated this requirement in the final regulations; and (d) One commenter requested that private employers, in addition to public entities, be required to furnish the HMO with a description of the health benefits that are required to be included in health benefits plans under State law or regulation. The Department notes that the reason that the regulation is limited to public entities is that there are laws or regulations in some States requiring certain benefits, including limitations and exclusions, that are applicable only to employees of public entities, in contrast with those laws or regulations requiring certain benefits that are applicable to all employees in a State. Since the Department believes that this latter, more general type of information is readily available to HMOs, it does not find it necessary to increase the burden on private employers by requiring them to furnish this information to the HMO.

6. Section 110.803(e) pertains to the notification of the HMO by the employing entity that the HMO's request for inclusion is inadequate. As noted above in section 5, the section has been modified, in response to public comment, to allow the employing entity 60 days to notify the HMO. Three commenters objected to this proposed section on the grounds that the HMO, and not the employing entity, should be responsible for submitting a valid request. The Department notes that the HMO is, of course, responsible for submitting an accurate request for inclusion. However, the Department believes that, if the employing entity intends to refuse to include the HMO alternative in its health benefits plan because it believes the HMO's request to be insufficient, it is only reasonable that the entity notify the HMO of the basis for its conclusion.

One commenter recommended that employing entities be allowed, as a condition of the HMO's participation in the health benefits plan, to make their own determinations as to the fiscal soundness of an HMO which has requested inclusion. The Department believes that this type of scrutiny of an HMO is unnecessary. It notes that federally qualified HMOs are required, under § 110.108(a) of the regulations, to have fiscally sound operations and that the Department monitors carefully their compliance with that requirement. Moreover, to permit each employing entity to make this determination as a requirement for the HMO's inclusion in the health benefits plan would lead to inconsistent determinations and would undermine the purposes of section 1310 by allowing the exclusion of HMOs that the Department has determined are eligible for inclusion.

7. Section 110.803(f) describes when an HMO must submit a new request for

inclusion in a health benefits plan of an employing entity. Four commenters recommended that, regardless of whether any employees enroll in the HMO during the initial offering, the entity should be required to continue to offer the HMO during the entire health benefits year so that new employees, transfers, and others who subsequently become eligible to enroll in the HMO (see § 110.806(e)(2) for a complete list) have the opportunity to do so. Other commenters took the opposite position; namely, that if the HMO does not get any enrollees during the initial offering period, it should have to submit a new request in order for any subsequently eligible employees to enroll. The Department believes that the former position reflects accurately the purposes of section 1310 of the Act in that it assures that more employees will be offered the option of membership in a qualified HMO. Accordingly, the regulation has been changed to require that the employees described in § 110.806(e)(2) be given the opportunity to enroll in the HMO during the entire health benefits year, regardless of whether any other employees of that entity have enrolled previously in the HMO.

8. Section 110.804 sets forth the details of how the HMO option is to be offered by the employing entity to its employees. One commenter suggested that, as a condition to the offering of the HMO, the HMO should be required to execute a contract with the employing entity binding the HMO to assure the delivery of health services to employees who subsequently enroll in the HMO. The Department notes that, in order to obtain Federal qualification, an HMO must provide assurances satisfactory to the Secretary that it will arrange for the provision of all medically necessary basic health services to its members. (See § 110.102(a)). Since the Department monitors, on an ongoing basis, the compliance of HMOs with their assurances, it does not believe that the contract suggested above between the employing entity and the HMO is necessary.

9. Section 110.805 describes which HMOs must be included in a health benefits plan. Paragraph (c) of this section, which is intended to promote competition among HMOs, describes alternate HMOs which may be offered by the employing entity instead of an HMO which made a timely request. A new section (c)(4) was proposed to limit the alternate HMOs which were otherwise eligible to be offered to those which were "included in the health benefits plan on terms no less favorable to the employing entity's employees (with regard to the employing entity's monetary contribution) than those on which the HMO submitting the timely request would have been included." A number of commenters objected to and suggested deletion of the proposed § 110.805(c)(4). They stated that the phrase "no less favorable" was ambiguous and could result in the offering of an alternate HMO that, even though the employer's monetary contribution was no less favorable to the employee, (a) underbid the timely HMO by offering employees a less favorable package of health benefits, or (b) was less favorable to employees in that it would cost them more out-of-pocket (e.g. for copayments).

The Department, while noting that § 110.805(c)(4) was intended to protect employees, acknowledges that the provision fails to contribute to that end because it does not protect employees in situations such as those described above. The Department has decided to delete this provision because of the difficulties inherent in trying to determine on a qualitative basis whether a plan is less favorable to an employee, and because it is not convinced that there is a problem with employer behavior in this regard. However, the Department is interested in receiving information from the public as to whether § 110.805(c) is being used in a manner that affects employees adversely. Upon receipt of such comments, it will reconsider what action, if any, is appropriate.

10. Section 110.806(a) requires that each employing entity provide each qualified HMO which is included in its health benefits plan with "fair and reasonable" access to eligible employees. The section then details what, at a minimum, this access shall include. While one commenter wanted the HMO's access to employees to be more flexible, others suggested that the term be defined in specific detail. The Department believes that the regulation adequately defines access by setting forth the minimum requirements for fair and reasonable access. It notes that an employing entity may, of course, agree to permit the HMO more favorable access than that required by the regulation.

11. Section 110.806(c), which sets forth the rules for the group enrollment period, requires the employing entity to have a group enrollment period with no waiting periods or exclusions or limitations based on health status as a condition of enrollment in the HMO or transfer to non-HMO coverage from an HMO. Two commenters recommended changing this section to allow a prospective HMO enrollee to remain with his original carrier if on the effective date of change to HMO coverage the enrollee is an inpatient and the original carrier responsibility continues through confinement. The Department notes that it has no authority to mandate the application of coordination of benefits agreements. However, as stated in § 110.806(c), nothing in these regulations prohibits voluntary agreements between HMOs and other carriers which are included in the health benefits plan, such as the one suggested above.

12. Section 110.806(d), as proposed, required the employing entity to "assure that employees selecting the option of HMO membership will not, because of this selection, lose their eligibility for other health benefits, such as dental or prescription drug coverage, for which they were previously eligible or would be eligible if selecting a non-HMO option and which are not included in the services provided by the HMO on a prepaid basis." This requirement, for convenience, will be referred to below as the "continued eligibility" requirement.

Twenty commenters addressed the continued eligibility requirement in their letters. The comments are summarized as follows: (a) One commenter urged the Department to retain the language as proposed, citing the requirement as critical for HMOs to compete in the marketplace; (b) one commenter, while approving the proposed regulation, urged its expansion to assure eligibility for any employment-related benefits; (c) five commenters objected to the provision, claiming it would unduly burden and result in additional administrative costs to employers; (d) eleven commenters felt the proposed regulation should be limited to "free-standing" or "self-contained" benefits, that is, benefits which are offered as a separate, discrete package and not integrated into a basic medical insurance policy or a major medical plan; many of these commenters requested clarification as to the level and scope of benefits the Department was proposing be subject to the requirement; and (e) four commenters urged that the requirement apply only to free-standing benefits, except that dental benefits should be extracted from a comprehensive package of indemnity benefits because the dental benefit is "significant."

The Department notes that the purpose of section 1310 and its implementing regulations is to assure that employees are given a true option to choose among competing alternatives in health benefits plans, including HMOs. The continued eligibility requirement, which assures that employees who choose to enroll in an HMO are not penalized by that choice with respect to free-standing health benefits available to employees is, among other provisions, a means of achieving that statutory purpose.

In light of the public comments received, however, the Secretary has revised the regulation to require an employing entity, at the request of the HMO, to provide for continued eligibility only as to those benefits which are "free-standing" and not offered by the HMO to its members as part of the HMO benefit package. The term "free-standing" is defined at § 110.806(d)(2). Further, the provision at § 110.806(d) is applicable only when the HMO does not offer a particular health benefit in whole or in part. Because, in the experience of the Department, this is most likely to occur with respect to the offering of three distinct health benefits, prescription drugs, dental services, and optical services, the Department has limited the applicability of § 110.806(d) to these benefits. Should the public submit information regarding any other free-standing health benefits for which employees selecting the HMO option would be likely, in the absence of the continued eligibility requirement, to lose their eligibility, the Department will consider further rulemaking to broaden the requirement.

In view of the response that this proposed section elicited, the Department believes that it is appropriate to clarify this section by adding to the regulation specific examples of what the employing entity is, and is not, required to continue to make available to its employees selecting an HMO option. This addition to the regulations includes examples showing when the employing entity is required to continue to make available the free-standing benefits not available through the HMO to its employees because the HMO option being offered does not provide for any level of that particular benefit. The regulation also includes examples showing when the employing entity need not continue to make available the free-standing, non-HMO coverage to employees selecting the HMO option.

In addition, as noted in one of the examples under § 110.806(d), nothing in this regulation requires that the coverage for the free-standing benefit be made optional (or mandatory) for employees selecting the HMO option if coverage for the benefit is not optional (or mandatory) for employees selecting the non-HMO option.

The Department also notes that § 110.806(d) does not address whether the employing entity must continue to make available to employees who select the HMO option non-health related benefits, such as life or disability insurance. While the Department has decided not to include in these regulations a requirement that employing entities continue to make these non-health benefits available, it is concerned that any employing entity that does not do so may be acting in a manner inconsistent with other Federal statutes. The Department intends to report any discriminatory or anti-competitive conduct to the appropriate Federal agencies for monitoring in this regard. Moreover, it notes that under § 110.808(c), the employing entity may only exclude from its contribution to the HMO option those portions of the contribution allocable to benefits (either related to health or not) for which eligible employees continue to be covered notwithstanding selection of the HMO option.

Finally, the Department notes that, while it is now limiting this requirement to free-standing benefits, the HMO and employer may agree to give employees access to coverage for an "integrated" benefit.

13. Section 110.806(e)(2) specifies when the employng entity shall make available the opportunity to select among different existing alternatives within a health benefits plan outside of the group enrollment period. Proposed § 110.806(e)(2)(ii) specified that this opportunity must be provided, among others, to eligible employees who, "have been transferred or have changed their place of residence, resulting in * * * loss of membership in a qualified HMO in which they were previously enrolled." A commenter noted that this language would not have given an otherwise eligible employee the opportunity to select a new option if he or she transferred or moved out of the service area of the HMO in which he or she was enrolled and was allowed by that HMO to retain membership. While this employee would not have lost membership in a qualified HMO, the services of the HMO would not longer be readily available and accessible since the employee would reside outside the HMO's service area. In order to accommodate this situation, the Department has changed the phrase, "resulting in loss of membership in a qualified HMO in which they were previously enrolled" to "resulting in residence outside the service area of a qualified HMO in which they were previously enrolled."

14. Section 110.806(e)(2)(iii) requires the employing entity to make available the opportunity to select among different existing alternatives within a health benefits plan to eligible employees who are covered by any alternative which ceases operation. One commenter felt this requirement should be deleted since it placed an unreasonable burden on employing entities. Another commenter suggested that the provision be amended to allow for a reasonable period of time for the transition of these employees to a new health benefits option. Since the Department believes that the section as proposed is reasonable in light of the importance of assuring that all employees are provided the opportunity for continuous health care coverage, it has not changed this section.

15. Two different proposed sections addressed the determination of which supplemental health services were to be included with the required basic health services in the HMO's prepaid benefit package. Proposed § 110.806(f)(3) would have allowed the HMO to select, for all employees, the supplemental health services to be included as part of its prepaid benefit package. Proposed § 110.808(a)(3) would have allowed the HMO to add supplemental health services to its prepaid benefit package if the amount of the HMO's premium is less than the employing entity's contribution to the HMO alternative. A number of commenters objected to these proposed rules on the following grounds: (a) They would only only increase the cost of health care but also eliminate the potential cost savings of offering an HMO, which is a major reason for the attractiveness of HMOs to employing entities; and (b) The inclusion of supplementals is more properly a subject for the negotiation process; in fact, allowing the HMO to select supplemental defeats the provisions of § 110.806(f) (1) and (2), which give the employing entity the right either to negotiate the supplemental health services to be offerd through its collective bargaining process or to select them through the same decision-making process it uses with respect to the non-HMO alternatives in its health benefits plan.

The Department notes that the HMO Amendments of 1976 (Pub. L. 94-460) amended section 1301(b)(1) of the Act to allow HMOs to include supplemental health services in their basic health services provided to their members for a basic health service payment. The Conference Committee, in its report adopting this provision as proposed by the House of Representatives, noted that the provision was necessary because "there are some States which require HMOs under State law to offer services which are not included among the defined basic health services." (H.R. Rep. #94–1513, 94th Cong., 2d Sess. 19 (1976)). The House Committee, in its report, explained its amendment by stating that "(It) would simplify the marketing of benefits by HMO's (sic) allowing them to choose a single benefits package which was competitive in the area which is served and to market that single package to all of its members. The present requirements (making the choice optional with members) have proved cumbersome for HMO's (sic) which find that each member, or group of members chooses a, different set of supplemental health services for which to contract, with the result that the HMO must provide and administer a great variety of different benefit packages to its different groups of members." (H.R. Rep. #94–518, 94th Cong., 1st Sess. 16 (1975)).

Thus, the legislative history shows clearly that Congress intended to allow HMOs to determine on a non-negotiable basis which supplemental health services to include in their prepaid benefit packages, if those supplemental services are (a) required to be offered under State law or (b) included uniformly by the HMO in the prepaid benefit package offered to all of its members.

Given this background, the Department has concluded that it is inappropriate to provide that the offering of all supplemental health services by the HMO is subject to negotiation. However, it does believe that it is consistent with section 1301(b)(1) of the Act and its legislative history to limit the HMO's right to determine on a non-negotiable basic which supplemental health services to include to the two situations described above.

In addition, based on the revision to § 110.808(d) ("Continued availability of other health benefits") described in item #12 above, the Department has concluded that a conforming amendment to this provision is appropriate. Accordingly, the Department has added a third situation in which the HMO may require the offering of certain supplemental health services as part of its basic health services package: When coverage for the supplemental health service at issue is available through the non-HMO option and that coverage is not available to employees selecting the HMO option. For example, if the coverage is available in an integrated (i.e., not free-standing) health service benefit plan, and thus is not required by § 110.806(d) to be made available to employees selecting the HMO option, the HMO may require the offering of this supplemental health service as part of its prepaid health services package. This result would also occur if the HMO and the employer had mutually agreed that the continued availability requirement of § 110.808(d) would not be applied with respect to a given supplemental health service.

A supplemental health service which did not fall in any of the three categories described above would properly be the subject of negotiation between the employing entity and the HMO, as well as the collective bargaining process, if any. The Department believes that this approach not only furthers the legislative intent by reducing the administrative burden on HMOs, but also does not interfere unduly with the employing entity's collective bargaining or other decision-making processes. Accordingly, § 110.806(f)(3) has been modified to reflect this approach.

Further, in light of the analysis set forth above, the Department has reconsidered the appropriateness of proposed § 110.808(a)(3) (which would have allowed HMOs to add prepaid supplemental health services so as to raise its premium up to the amount of the employing entity's contribution to the non-HMO alternative). Consistent with the revision to § 110.806(f)(3), proposed § 110.808(a)(3) has been deleted.

16. Section 110.808(a) sets forth the general principles for determining the employing entity's contribution to the HMO option. Proposed subparagraph (2) of that section stated that the amount of this contribution shall be equal, in terms of dollars, "to the largest amount of contribution per employee paid to any other option which is available to all eligible employees included in the health benefits plan * * *" (up to the amount of the HMO's premium). A number of commenters noted that using "all eligible employees" as a standard for determining contribution was not only inequitable but also would have an inflationary impact on those companies which determine their contributions based on the earning levels of each particular employee. Since the Department agrees with these commenters, it has changed § 110.808(a)(2) to require contribution by the employing entity based on the largest amount of contribution "for that individual employee".

17. Proposed § 110.808(a)(4) (now § 110.808(a)(3)) required the employing entity to increase the amount of its contribution for the HMO option whenever its contribution to other alternatives in its health benefits plan increases (up to the amount of the HMO premium). A number of commenters objected to this provision because they believe it to be inflationary and likely to be detrimental to the relationship between HMOs and employers. They also pointed out that applying this requirement in the middle of the health benefits year might result in altering an employing entity's contribution which was fixed by a contract with the HMO. Other commenters suggested that the Department add that the employing entity has the right to decrease the amount of its contribution for the HMO option whenever its contribution to other health plan alternatives decreases.

The Department believes that these comments have merit with respect to the proposed rule's applicability to the case where the employing entity's contribution to the HMO option is fixed by contract. Accordingly, the Department had decided to modify the provision. The employing entity is now required to increase its contribution to the HMO option during the health benefits year unless (a) the employing entity's contribution is fixed by contract or other arrangement with the HMO, or (b) the employing entity and HMO come to any other agreement on this issue. Of course, if the employing entity's contribution to the non-HMO alternative is to be revised only prospectively for the following health benefits year, then this revised contribution is to be used in determining the employing entity's contribution for the HMO premium. (See § 110.808(g)(1).) The Department also notes that while nothing in the statute or regulations prohibits an employing entity from decreasing its contribution to the HMO option at the time that its contribution to its other alternatives decreases, the parties may, of course, provide otherwise.

Finally, the Department encourages HMOs and employing entities to make provisions in advance on the subject of adjustments to the contribution rate in the event that the employing entity's contribution to other alternatives in its health benefits plan changes midterm during the health benefits year. It believes that agreement in advance on this issue would be beneficial to the relationship between HMOs and employing entities.

18. At the same time that the proposed subpart H rules were published, § 110.809 was promulgated as a final

regulation. (44 FR 42082, July 18, 1979). This section sets forth the conditions under which an employer must arrange for its employees' contributions for membership in a qualified HMO to be paid through payroll deductions. Although § 110.809 was effective immediately, it was also included in the NPRM, and the Department requested comments on it as well as on the proposed amendments to subpart H. The Department received the following comments on this provision: (a) A recommendation for deletion on the basis that the cost of setting up payroll deductions for a number of small HMOs would be prohibitive; (b) a suggestion that a grace period of one year be allowed for an employer to implement a payroll deduction system where one does not presently exist; and (c) a suggestion that a minimum number of enrollees in the HMO be required before the employing entity had to offer a payroll deduction. The Department notes that neither the statute (section 1310(c)) nor the regulation requires an employing entity to institute a payroll deduction system for HMO enrollees if it doesn't already provide such a system for paying employees' contributions for other options in the health benefits plans. The first and second suggestions are therefore not appropriate. The Department cannot adopt the suggestion in the third comment because it is inconsistent with section 1310(c).

19. The Department has also made certain minor technical and editorial changes.

The Assistant Secretary for Health of the Department of Health and Human Services, with the approval of the Secretary of Health and Human Services, amends 42 CFR Part 110, Subpart H, as set forth below.

Dated: June 30, 1980.

**Julius B. Richmond,**

*Assistant Secretary for Health.*

Approved: October 21, 1980.

**Patricia Roberts Harris,**

*Secretary.*

### Subpart H—Employees' Health Benefits Plans

Sec.

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**Authority**: Sec. 215, 58 Stat. 690 (42 U.S.C. 216); secs. 1301–1318, as amended, 92 Stat. 2131–2141 (42 U.S.C. 300e–300e–17)

### Subpart H—Employees' Health Benefits Plans

#### § 110.801 Definitions.

In addition to the terms defined in § 110.101 and 110.602, as used in this subpart:

"Bargaining representative" means a representative designated or selected for the purposes of collective bargaining under the National Labor Relations Act, as amended, (29 U.S.C. 151 *et seq.*) or under the Railway Labor Act, as amended, (45 U.S.C. 151 *et seq.*) or under a public entity collective bargaining agreement, or under the laws of any State or political subdivison thereof, or other employee representative designated or selected under any law.

"Carrier" means a voluntary association, corporation, partnership, or other organization which is engaged in providing, paying for, or reimbursing all or part of the cost of health benefits under group insurance policies or contracts, medical or hospital service agreements, membership or subscription contracts, or similar group arrangements, in consideration of premiums or other periodic charges payable to the carrier.

"Collective bargaining agreement" means an agreement entered into between an employing entity and the bargaining representative of its employees, and includes agreements entered into on behalf of groups of employing entities with the bargaining representative of their employees in accordance with the provisions of the National Labor Relations Act, as amended (29 U.S.C. 151 *et seq.*), or the Railway Labor Act, as amended, (45 U.S.C. 151 *et seq.*) or the laws of any State or political subdivision thereof.

"Designee" means any person or entity authorized to act on behalf of an employing entity or a group of employing entities to offer the option of membership in a qualified health maintenance organization to their eligible employees.

"Eligible employee" means an employee who is eligible to participate in a health benefits plan.

"Employee" means any individual employed by an employer or public entity on a full- or part-time basis.

"Employer" shall have the meaning given that term in Section 3(d) of the Fair Labor Standards Act of 1938, as amended, (29 U.S.C 203(d), 203(x)), except that the term "employer" does not include (1) the Government of the United States, the government of the District of Columbia or any territory or possession of the United States, a State or any political subdivision thereof, or any agency or instrumentality (including the United States Postal Service and Postal Rate Commission) of any of the foregoing; or (2) a church, convention or association of churches, or any organization operated, supervised, or controlled by a church, convention, or association of churches which organization (i) is an organization described in section 501(c)(3) of the Internal Revenue Code of 1954, and (ii) does not discriminate (A) in the employment, compensation, promotion, or termination of employment of any personnel, or (B) in the extension of staff or other privileges to any physician or other health personnel, because such persons seek to obtain or obtained health care, or participate in providing health care, through an HMO.

"Employing entity" means an employer or public entity.

"Employing entity-employee contract" means a legally enforceable agreement (other than a collective bargaining agreement) between an employing entity and its employees for the provision of, or payment for, health benefits for its employees, or for its employees and their eligible dependents.

"Group enrollment period" means the period of at least 10 working days each calendar year during which each eligible employee is given the opportunity to select among the alternatives included in a health benefits plan.

"Health benefits" means health benefits and services.

"Health benefits contract" means a contract or other agreement between an employing entity or a designee and a carrier for the provision of, or payment for, health benefits to eligible employees or to eligible employees and their eligible dependents.

"Health benefits plan" means any arrangement for the provision of, or payment for, any of the basic and supplemental health benefits described in §§ 110.102 and 110.103 of this Part offered to eligible employees, or to eligible employees and their eligible dependents, by or on behalf of an employing entity.

"Public entity" means a State as defined by section 2(f) of the Public Health Service Act (42 U.S.C. 201(f)), a political subdivision of a State, or any agency or instrumentality of the foregoing. "Political subdivision" includes counties, parishes, townships, cities, municipalities, towns, villages, and incorporated villages.

"To offer a health benefits plan" means to make participation in a health benefits plan available to eligible employees, or to eligible employees and their eligible dependents, and to make a financial contribution to the plan whether the financial contribution by the employing entity on behalf of these employees is made directly or indirectly, (e.g. through payments on any basis into a health and welfare trust fund).

### § 110.802 Applicability.

The regulations of this subpart apply in each calendar year to:

(a) Each employer which was required during any calendar quarter of the previous calendar year to pay its employees the minimum wage specified by Section 6 of the Fair Labor Standards Act of 1938 (or would have been required to pay its employees the minimum wage but for Section 13(a) of that Act) and which during any calendar quarter of the previous calendar year employed an average of not less than 25 employees; and

(b) Each public entity, as a condition of the payment to the State of funds under Sections 314(d), 317, 318, 1002, 1525, or 1610 of the Public Health Service Act, which during any calendar quarter of the previous calendar year employed an average of not less than 25 employees, if the employer or public entity:

(1) Offers, or if there is offered on behalf of the employer or public entity, in the calendar year beginning after any calendar quarter of the previous calendar year in which the employer or public entity employed an average of not less than 25 employees, a health benefits plan to its eligible employees; and

(2) Has received a written request for inclusion in the employer's or public entity's health benefits plan (which request meets the requirements of § 110.803) from one or more qualified HMOs which provide basic health services in an HMO service area in which at least 25 employees of the employer or the public entity, respectively, reside.

### § 110.803 Requirements for a request for inclusion of the HMO option in a health benefits plan; employing entity response.

(a) *Time limitations.* (1) Unless otherwise agreed to by the HMO and the employing entity or designee, an HMO's request for inclusion in an employing entity's health benefits plan must be received by the employing entity or designee no more than 365 days and not less than 180 days before the expiration or renewal date of a health benefits contract or employing entity-employee contract, and no more than 365 days and not less than 180 days before the expiration date of a collective bargaining agreement, or in the case of a public entity, such longer period as may be prescribed by State law.

(2) For the purposes of this paragraph:

(i) A collective bargaining agreement that is automatically renewable or without fixed term shall be treated as having an expiration or renewal date on the earliest anniversary date of the collective bargaining agreement.

(ii) A collective bargaining agreement that is for a fixed term in excess of one year and provides that its terms regarding health benefits may be renegotiated during the term of the agreement shall be treated as having an expiration or renewal date at the time provided by the agreement for discussion of these changes.

(b) *To whom the written request is to be directed.* The request for inclusion must be in writing and (1) in the case of an employer, be directed specifically to the employer's managing official at the employer site being solicited or to the employer's designee; and (2) in the case of a public entity, be directed to the Chief Executive Officer of the public entity, or to the public entity's designee.

(c) *Information which the request must include.* The request must (1) Provide evidence that the Secretary has determined that the HMO is a qualified HMO in accordance with section 1310(d) of the Act and Subpart F of this part;

(2) Describe the HMO's service area or proposed service area and give the dates basic and supplemental health services will be provided in the area or areas;

(3) Indicate whether the services of health professionals which are provided as basic health services are provided through health professionals who are (i) members of the staff of the organization, or (ii) members of a medical group(s), or (iii) members of an individual practice association(s), or (iv) health professionals who have contracted with the HMO for the provision of these services or (v) any combination of the above;

(4) If the HMO provides health services through an individual practice association(s), provide a listing of member physicians by name, specialty, and whether they are accepting new patients from the HMO membership. This listing must be current within 90 days of the date of the request for inclusion;

(5) If the HMO provides health services other than through an individual practice association, provide for each ambulatory care facility the facility's address, days and hours of operation, a statement whether it is accepting new patients from the HMO membership, and the names and specialities of the facility's providers of basic and supplemental health services. This information must be current within 90 days of the date of the request for inclusion;

(6) List the hospitals where HMO members will be provided basic and supplemental health services;

(7) Identify (i) the nature of the HMO entity, i.e., for profit or non-profit, public or private, sole proprietorship, partnership, or stock or non-stock corporation, , (ii) the members of the HMO's policymaking body, and (iii) the principal managing officer of the HMO;

(8) Provide a statement of the HMO's capacity to enroll new members and the likelihood of any future limitations on enrollment;

(9) Provide the HMO's most recently audited annual financial statements;

(10) Provide proposed implementing agreements between the HMO and the employer, public entity, or designee for the HMO offering;

(11) Provide sample copies of solicitation brochures and membership literature which will be used in the offer of the HMO alternative to employees;

(12) State either (i) the HMO's current rates, including copayments, if any, for basic (and uniformly included supplemental) health services and the dates these rates became effective, or (ii) the HMO's estimated rates for these services.

(d) *Employing entity response.* An employing entity or designee shall respond in writing to an HMO's request for inclusion no later than 60 days after the receipt of the request and shall state whether the employing entity has 25 or more employees who reside within the service area of the HMO. If so, the employing entity or designee shall also state the expiration or renewal dates of its health benefits contracts, employer-employee contracts, and public entity-employee contracts covering these employees, the amount of the employing entity's current contribution (and, where applicable, the employee's contribution) for health benefits, including the dates those contribution levels became effective, and the expiration dates of any collective bargaining agreements covering these employees. In addition, in this response, a public entity or its designee shall furnish the HMO with a description of health benefits, including limitations and exclusions, required under State law or regulation for health benefits plans for employees of the public entity.

(e) *Effect of inadequate request.* If the request for inclusion does not meet the requirements of paragraphs (a)–(c) of this section, the employing entity is not required to include the HMO alternative in its employees' health benefits plan under § 110.805 until the HMO makes its request in accordance with those paragraphs. In such a case, the employing entity or its designee shall, within 60 days after receipt of the request, notify the HMO in writing of the basis for its conclusion that the request does not meet the requirements of paragraphs (a)–(c) of this section.

(f) *New request for inclusion.* If an employing entity includes the HMO alternative in a health benefits plan in accordance with a request meeting the requirements of paragraphs (a)–(c) of this section, the employing entity shall offer the HMO alternative to the employees described in § 110.806(e)(2) during the entire health benefits year. However, if no employees enroll during the health benefits year, the HMO seeking inclusion in the health benefits plan for subsequent enrollment periods shall submit a new request in accordance with paragraphs (a)–(c) of this section.

(g) *Discretionary offering of HMO alternative.* Nothing in this subpart prevents the employing entity or designee from offering the HMO alternative at any time by mutual agreement with the HMO.

### § 110.804 Offer of HMO option to employees.

(a) *Inclusion of HMO option.* An employing entity subject to § 110.802 shall, at the time a health benefits plan is offered to its eligible employees, include in the plan the option of membership in qualified HMOs in accordance with this section.

(b) *Employees to whom the HMO option must be offered.* Each employing entity subject to this subpart shall offer the option of membership in a qualified HMO to each eligible employee, or to each eligible employee and his or her eligible dependents, who reside within the service area of the qualified HMO being offered.

(c) *Manner of offering the HMO option.* (1) For the employees of an employing entity subject to this subpart who are represented by a bargaining representative, the offer of membership in a qualified HMO (i) must first be made to the bargaining representative, and (ii) if the offer is accepted by the representative, must then be made to each represented employee.

(2) For those employees not represented by a bargaining representative, the offer must be made directly to those employees in accordance with this subpart.

### § 110.805 HMOs which must be included in a health benefits plan.

(a) *HMOs providing basic health services through varying arrangements with health professionals.* If more than one qualifed HMO engaged in the provision of basic health services in an area in which eligible employees of an employing entity subject to this subpart reside has requested inclusion in the employer's or public entity's health benefits plan as provided by § 110.802(a)(2)(ii), and if:

(1) One or more of these organizations provides basic health services through physicians or other health professionals who are members of the staff of the organization or a medical group (or groups), and

(2) One or more of these organizations provides basic health services through (i) an individual practice association (or associations), or (ii) a combination of such an association (or associations), medical group (or groups), staff, and individual physicians and other health professionals under contract with the organization, then, of the qualified HMOs included under this section in a health benefits plan of an employing entity subject to this subpart, at least one shall be an organization which provides basic health services as described in subparagraph (1) of this paragraph and at least one shall be an organization which provides basic health services as described in subparagraph (2) of this paragraph. For purposes of this paragraph, individual physicians and other health professionals who have contracted with the HMO do not include health professionals who are members of the HMO's staff, of medical groups, or of entities which would be medical groups but for the requirements of subparagraph (3)(i) of the definition of medical group in § 110.101.[1]

(b) *Additional HMOs which must be included.* An employing entity subject to this subpart shall offer the option of membership in additional qualified HMOs to its eligible employees, described in subparagraphs (1) and (2) of this paragraph, if the additional qualified HMOs demonstrate that their service areas include the place of residence of at least 25 employees of the employing entity:

(1) Who do not reside in the service area of qualified HMOs already included in the employing entity's health benefits plan; or

(2) To whom membership in qualified HMOs already included in the health benefits plan is not available because these HMOs have closed their enrollment of additional eligible employees of the employing entity.

(c) *Alternate HMOs which may be included.* An employing entity subject to this subpart is not required to include in the health benefits plan offered to eligible employees the option of membership in the specific qualified HMO which initiated the request for inclusion in the health benefits plan if (1) the employing entity or designee includes in the health benefits plan the option of membership in one or more other qualified HMOs that may not have made a request within the time limit of § 110.803(a) but are willing to be included, (2) these latter HMOs are of the same type (i.e., as described in paragraph (a)(1) or (2) of this section) as the HMO which submitted the timely request, and (3) all of the employees of the employing entity residing in the service area of the HMO submitting the timely request reside in areas served by these latter HMOs.

### § 110.806 How the HMO option is to be included in the health benefits plan.

(a) *HMO access to employees.* The employing entity shall provide each qualified HMO which is included in its health benefits plan with fair and reasonable access, not less than 30 days prior to and during the group enrollment period, to employees referred to in § 110.804(b) for purposes of presenting and explaining its program in accordance with § 110.108(c) of this Part. This access shall include, at a minimum, the opportunity for the distribution of educational literature, brochures, announcements of meetings, and other relevant printed materials meeting the requirement of § 110.108(c) to each employee referred to in § 110.804(b). In no event shall the employing entity provide qualified HMOs access to eligible employees which is more restrictive or less favorable than the access it provides other offerors of alternatives included in the health benefits plan, whether or not these offerors elect to avail themselves of that access.

(b) *Review of HMO offering materials.* The HMO shall give the employing entity or designee the opportunity to review, revise, and approve HMO educational and offering materials before distribution. Revisions shall be limited to correcting factual errors and misleading or ambiguous statements, unless otherwise agreed to by the HMO and the employer or public entity or designee, or as may be required by law. The employing entity or designee shall complete promptly any of these revisions in the offering material so as not to delay or otherwise interfere with the group enrollment period.

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[1] These requirements are that the members of the medical group "as their principal professional activity (over 50 percent individually) engage in the coordinated practice of their profession and as a group responsibility have substantial responsibility (over 35 percent in the aggregate of their professional activity) for the delivery of health services to members of an HMO."

(c) *Group enrollment period; prohibition of waiting periods, exclusions, and limitations.* An employing entity or designee including the option of membership in a qualified HMO under this subpart as part of the health benefits plan offered to its eligible employees shall provide for a group enrollment period, prior to the effective date of the HMO coverage established under paragraph (g) of this section, without application of waiting periods or exclusions or limitations based on health status as a condition of enrollment in the HMO or transfer to non-HMO coverage from an HMO. Nothing in this subpart precludes the uniform application of coordination of benefits agreements between the HMOs and the other carriers which are included in the health benefits plan.

(d) *Continued availability of other health benefits.* (1) At the request of a qualified HMO, the employing entity or its designee shall provide that employees selecting the option of HMO membership will not, because of this selection, lose their eligibility for free-standing dental, optical, or prescription drug benefits for which they were previously eligible or would be eligible if selecting a non-HMO option and which are not included in the services provided by the HMO to its members as part of the HMO prepaid benefit package.

(2) For purposes of this paragraph, the term "free-standing" refers to a benefit which (i) is not integrated or incorporated into a basic health benefits package or major medical plan, and (ii) is either (A) offered by a carrier other than the one offering the basic health benefits package or major medical plan, or (B) subject to a separate premium from the premium for the basic health benefits package or major medical plan.

Illustrative Examples: Set forth below are examples of the employing entity's obligation with respect to the continued eligibility of employees selecting the HMO option for these free-standing health benefits:

1. The health benefits plan includes a free-standing dental benefit. The HMO does not offer any dental coverage as part of its health services provided to members on a prepaid basis. The employing entity must provide for the continued eligibility of those employees selecting the HMO option for dental coverage.

**Note:** If the dental coverage is not optional for employees selecting the non-HMO option, nothing in this regulation requires that the coverage be made optional for employees selecting the HMO option. Conversely, if this coverage is optional for employees selecting the non-HMO option, nothing in this regulation requires that the coverage be mandatory for employees selecting the non-HMO option.

2. If the non-HMO option provides free-standing coverage for optical services (such as refraction and the provision of eye glasses), and the HMO does not, the employing entity must provide for the continued eligibility for those employees selecting the HMO option for optical coverage.

3. The non-HMO option includes dental coverage in its major medical package, with a common deductible applied to dental as well as non-dental benefits. The HMO provides no dental coverage as part of its prepaid health services. Because the dental coverage is not free-standing, the employing entity is not required to provide for the continued eligibility for dental coverage for those employees selecting the HMO option, although it is free to do so.

(e) *Affirmative written selections.* (1) During the group enrollment period in which the alternative of membership in any particular qualified HMO is offered to an eligible group of employees for the first time, the employing entity or designee shall present the health benefits plan alternatives to each eligible employee residing in the service area of the HMO with the requirement that an affirmative written selection be made among the different alternatives included in the health benefits plans. In subsequent group enrollment periods, it shall make available a selection among the alternatives; however, a written selection is required only when the eligible employee elects to change from one alternative to another.

(2) In addition to the group enrollment period, the employing entity or designee shall make available the opportunity to select among different existing alternatives within a health benefits plan to eligible employees who: (i) Are new employees, (ii) have been transferred or have changed their place of residence, resulting in eligibility for membership in a qualified HMO for which they were not previously eligible by place of residence, or resulting in residence outside the service area of a qualified HMO in which they were previously enrolled, or (iii) are covered by any alternative which ceases operation. At the time these employees are eligible to participate in the health benefits plan, the employing entity or designee shall make available, without waiting periods or exclusions or limitations based on health status as a condition, the opportunity to enroll in an alternative HMO or transfer to a non-HMO coverage from an HMO, and shall require these employees to make an affirmative written selection among the different alternatives included in the health benefits plan.

(f) *Determination of copayment levels and supplemental health services.* The selection of a copayment level and of supplemental health services to be contracted for is to be made as follows:

(1) For those employees represented by a collective bargaining representative, the selection of copayment levels and supplemental health services is subject to the collective bargaining process.

(2) For those employees not represented by a bargaining representative, the selection of copayment levels and supplemental health services to be offered to eligible employees is subject to the same decisionmaking process used by the employing entity with respect to the non-HMO alternatives in its health benefits plan.

(3) In all cases, the HMO has the right to include with its basic health services provided to its members for a basic health services payment, on a non-negotiable basis, those supplemental health services (i) that are required to be offered under State law, or (ii) that are included uniformly by the HMO in its prepaid benefit package, or (iii) coverage for which is available to employees selecting the non-HMO option but not available to employees selecting the HMO option.

(g) *Effective date of coverage.* Unless otherwise agreed to by the employing entity, or designee, and the HMO, the effective date of coverage by the HMO for employees selecting the HMO option shall begin on the day the non-HMO coverage expires or is renewed without lapse.

### § 110.807 When the HMO is to be offered to employees.

The employing entity or designee shall offer eligible employees the option of membership in a qualified HMO at the earliest date permitted under the terms of existing collective bargaining agreements, employer-employee or public entity-employee contracts, or contracts for health benefits. Should the HMO's request for inclusion in a health benefits plan be received at a time when these existing contracts or agreements do not provide for including a qualified HMO in the health benefits plan, the inclusion of the HMO in the health benefits plan shall occur at the time that new agreements or contracts are offered or negotiated and shall be consistent with the following paragraphs:

(a) Unless mutually agreed otherwise, if a collective bargaining agreement is in

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force at the time the request for inclusion in the health benefits plan is made by the HMO to the employing entity or designee, the request shall be raised in the collective bargaining process (1) when a new agreement is negotiated, (2) if the agreement is for a fixed term in excess of one year and provides that its terms regarding health benefits may be renegotiated during the term of the agreement, at the times provided by the agreement for discussion of these changes, or (3) in accordance with a specific process to review HMO offers.

(b) Unless mutually agreed otherwise, for those employees not covered by a collective bargaining agreement, the employing entity or designee shall include the HMO option in any health benefits plan offered to eligible employees when the existing employer-employee contract or public entity-employee contract is renewed or when a new health benefits contract or other arrangement is negotiated. If an employer-employee or public entity-employee contract or a health benefits contract has no fixed term or has a term in exess of one year, the contract shall be treated as renewable on its earliest anniversary date. If the employing entity or designee is self-insured, the budget year shall be treated as the term of the existing contract.

(c) Unless mutually agreed otherwise, for employing entities with multiple contracts or other arrangements included as part of the health benefits plan which may have different expiration or renewal dates, the employing entity shall include the HMO option, in accordance with paragraphs (a) and (b) of this section, for each contract or arrangement at the time the contract or arrangement is renewed or reissued or the benefits provided under the contract or arrangement are offered to employees.

### § 110.808 Contributions for HMO option.

(a) *General principles.* (1) The employing entity or designee shall include the HMO option in the health benefits plan on terms no less favorable, with respect to the employing entity's monetary contribution or designee's cost for health benefits calculated in dollars and cents, than those on which the other alternatives in the health benefits plan are included. However, the employing entity or designee is not required to pay more for health benefits as a result of offering the option of membership in a qualified HMO than it would otherwise be required to pay for health benefits by a collective bargaining agreement or other employer-employee contract or public entity-employer contract in effect at the time the HMO is included in the health benefits plan.

(2) An employing entity or designee which calculates the health benefits contribution on a per employee earnings level basis must apply that same calculation to the HMO contribution. The amount of the employing entity's or designee's contribution per employee for the HMO option must be equal, in terms of dollars and cents, to the largest amount of the contribution that would be paid for that individual employee to any other alternative which is included in the health benefits plan, but shall not be required to exceed the amount of the HMO premium.

(3) The employing entity or designee shall increase the amount of its contribution for the HMO option at the time the contribution to other alternatives in the health benefits plan increases (up to the amount of the HMO premium), unless (i) the employing entity's or designee's contribution is fixed by a contract or other arrangement between the employing entity or designee and the HMO, or (ii) otherwise agreed to by the employing entity or designee and the HMO.

(b) *Administrative expenses.* The employing entity or designee may not consider administrative expenses incurred in connection with offering any alternative in the health benefits plan in determining the amount of its contribution to the HMO. However, if the employing entity or designee has special requirements for other than standard solicitation brochures and membership literature, it shall determine and distribute any administrative costs attributable to these requirements, in the case of the offering of the HMO option, in a manner consistent with its method of determining and distributing these costs for the non-HMO alternatives.

(c) *Exclusion for contribution for certain benefits.* In determining the amount of the employing entity's contribution or designee's cost for the HMO option, the employing entity or designee may exclude those portions of the contribution allocable to benefits (e.g., life insurance or insurance for supplemental health benefits) for which eligible employees or eligible employees and their eligible dependents will be covered notwithstanding selection of membership in an HMO, and which are not offered on a prepaid basis by the HMO to the employing entity's employees.

(d) *Contributions determined by collective bargaining agreements or by other contracts or by law.* Where the specific amount of the employing entity's contribution for health benefits is fixed by a collective bargaining agreement, by an employer-employee or public entity-employee contract, or by. law, the amount so determined shall constitute the employing entity's obligation for contribution toward the HMO premiums on behalf of eligible employees or eligible employees and their eligible dependents.

(e) *Allocation of portion of a contribution determined by a collective bargaining agreement.* Where the employing entity's contribution for health benefits is determined by a collective bargaining agreement, but the amount so fixed includes contribution for benefits in addition to health benefits, the employing entity shall determine, or shall instruct its designee to determine, the portion of its contribution applicable to health benefits in accordance with paragraph (g) of this section.

(f) *Contributions not determined by collective bargaining agreements or by other contracts or by law.* For employees not covered by a collective bargaining agreement, employer-employee or public entity-employee contract, or by a law specifying the contribution for health benefits, the employing entity's contribution to the HMO on behalf of eligible employees or eligible employees and their eligible dependents shall be determined in accordance with paragraphs (a), (b), (c), and (g) of this section on the basis of the total cost of providing the health benefits offered to the employees for the most recent period for which experience is available.

(g) *Calculation of cost.* An employing entity's contribution or designee's cost for alternatives other than the qualified HMO, included in the health benefits plan shall be determined in the following manner, unless otherwise agreed to by the HMO and the employing public entity or designee:

(1) *Prospective calculation.* If the employing entity's contribution or designee's cost for non-HMO alternative health benefits is determined solely on the basis of a fixed prospective amount (not subject to retrospective adjustment) then the amount of the prospective payment made by or on behalf of the employing entity to the non-HMO alternative for the provision of health benefits to eligible employees or to eligible employees and their eligible dependents shall constitute the employing entity's contribution toward the HMO premium.

(2) *Retrospective calculation.* If the employing entity's contribution or designee's cost for non-HMO alternative health benefits is determined by a contract with a carrier on any form of retrospective experience rating basis,

including any determination of current premiums which reflects, takes into account, or is otherwise based on any form of supplementation or any rebate, refund or other redistribution of premiums collected in any previous year for which experience is available, any billing contract arrangement, any plan of self-insurance, any direct service plan provided by the employing entity or designee, or any other form of health benefits plan wherein the actual cost to the employing entity or designee is determined retrospectively, an estimated cost shall be used to determine the obligation for contribution toward the HMO premium. The employing entity or designee shall determine this estimated cost based on consideration of the following factors: (i) The employing entity's or designee's cost experience for the non-HMO alternatives with respect to the most recent benefit period for which the experience is available at the time when the employing entity's prospective contribution or designee's obligation to the HMO is to be determined; (ii) a reasonable allowance for inflation based on historical cost trends and the anticipated future costs increases; (iii) where applicable and consistently applied, cost differences experienced in the provision of health benefits for separate regional or local areas of employment; (iv) anticipated changes in the composition and experience of the covered population actually being served by the non-HMO alternatives attributable to the shift of enrollment to the HMO; (v) any changes in health benefits to be provided by the non-HMO alternatives during the period for which the estimated contribution is to be determined; (vi) any other anticipated material change in the experience rating basis under any health benefits contract for the benefits period.

(h) *Retention of data.* An employing entity or designee shall retain the data used to compute its level of contribution to the alternatives included in the health benefits plan for three years. The Secretary may review this data either on her own initiative or in response to a request to the Secretary from an HMO or an employee of the employing entity which sets forth reasonable grounds supporting the request to determine whether the level of contributions determined by the employing public entity or designee complies with this subpart.

### § 110.809 Payroll deductions.

Each employing entity which provides payroll deductions as a means of paying employees' contributions for health benefits or which provides a health benefits plan to which an employee contribution is not required, and which is required by § 110.802(a) to offer its employees the option of membership in a qualified HMO, shall, with the consent of an employee who exercises this option, arrange for the employee's contribution, if any, for HMO membership to be paid through payroll deductions.

### § 110.810 Relationship of Section 1310 of the Public Health Service Act to the National Labor Relations Act, as amended, and the Railway Labor Act, as amended.

The obligation of an employing entity subject to this subpart to include the option of membership in a qualified HMO in any health benefits plan offered to its eligible employees shall be carried out consistently with the obligations imposed on that employing entity under the National Labor Relations Act, the Railway Labor Act, and other laws of similar effect.

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~~(2) If the employer's or public entity's contribution or designee's cost for health benefits with respect to the non-health maintenance organization alternative is determined by a contract with a carrier on any form of retrospective experience rating basis, any billing contract arrangement, any plan of self-insurance, any direct service plan provided by the employer or public entity or designee, or any other form of health benefits plan wherein the actual cost to the employer or public entity or designee is determined retrospectively, an estimated cost shall be used to determine the obligation for contribution toward the health maintenance organization's dues or premiums. This estimated cost shall be determined by the employer or public entity or designee based on consideration of the following factors:~~

~~(i) The employer's or public entity's or designee's cost experience for the non-health maintenance organization alternative with respect to the most recent benefit period for which the experience is available at the time when the employer's or public entity's prospective contribution or designee's obligation to the health maintenance organization is to be determined;~~

~~(ii) A reasonable allowance for inflation based on historical cost trends and anticipated future cost increases;~~

~~(iii) Where applicable and consistently applied, cost differences experienced in the provision of health benefits for separate regional or local areas of employment;~~

~~(iv) Anticipated changes in the composition and experience of the covered population actually being served by the non-health maintenance organization alternative attributable to the shift of enrollment to the health maintenance organization;~~

~~(v) Any changes in health benefits to be provided by non-health maintenance alternatives during the period for which the estimated contribution is to be determined; and~~

~~(vi) Any other anticipated material change in the experience rating basis under any health benefits contract for the benefit period.~~

~~(g) An employer or public entity or designee shall retain for at least three years the data used to compute its level of contribution to the alternatives included in the health benefits plan. This data may be reviewed by the Secretary either on his own initiative or in response to a request which sets forth reasonable grounds supporting the request, to determine whether the level of contributions determined by the employer or public entity complies with this subpart.~~

### ~~§ 110.808 Relationship of section 1310(a) of the Public Health Service Act to the National Labor Relations Act as amended and the Railway Labor Act, as amended.~~

~~The obligation of an employer or public entity subject to this subpart to include the option of membership in a qualified health maintenance organization in any health benefits plan offered to its eligible employees shall be carried out consistently with the obligations imposed on such employer or public entity under the National Labor Relations Act and the Railway Labor Act, or other law of similar effect.~~

### ~~§ 110.809 Payroll deductions.~~

~~Each employing entity which provides payroll deductions as a means of paying employees' contributions for health benefits or which provides a health benefits plan to which an employee contribution is not required, and which is required by § 110.802(a) to offer its employees the option of membership in a qualified HMO, shall, with the consent of an employee who exercises this option, arrange for the employee's contribution, if any, for HMO membership to be paid through payroll deductions.~~

~~(Sec. 215, 58 Stat. 690 (42 U.S.C. 216); secs. 1301-1318, as amended, 92 Stat. 2131-2141 (42 U.S.C. 300e-300e-17))~~

~~[44 FR 42082, July 18, 1979]~~

## Subpart I—Continued Regulation of Health Maintenance Organizations and Other Entities

AUTHORITY: Sec. 215, 58 Stat. 690 (42 U.S.C. 216); secs. 1301-1316, as amended, 90 Stat. 1945-1960 (42 U.S.C. 300e-300e-15).

SOURCE: 43 FR 32255, July 25, 1978, unless otherwise noted.

### § 110.901 Purpose and applicability.

This subpart applies to any entity which was determined by the Secretary to be a qualified health maintenance organization (HMO) under subpart F of this part, or which provided written assurances to the Secretary as a condition for receiving financial assistance under subparts C, D, or E of this part, and sets forth procedures for enforcing the assurances given to the Secretary by these entities.

### § 110.902 Compliance with assurances.

Any entity subject to this subpart shall comply with the assurances which it provided to the Secretary, unless compliance is waived under § 110.907.

### § 110.903 Reporting requirements.

Entities subject to this subpart shall submit:

(a) The reports which may be required by the Secretary under § 110.108(o), and,

(b) Any additional reports the Secretary may reasonably require.

### § 110.904 Enforcement procedures.

(a) *Complaints.* Any person, group, association, corporation, or other entity may file a written complaint with the Secretary with respect to the compliance of any entity with assurances it gave to the Secretary under this part. A complaint shall state the grounds and underlying facts of the complaint, the names of all persons involved, and that all appropriate grievance and appeals procedures established by the entity and available to the complainant have been exhausted.

(b) *Investigations.* The Secretary may initiate investigations when, based on a report, a complaint, or any other information, he has reason to believe that an entity subject to this subpart is not in compliance with any assurances it gave to the Secretary under this part. The Secretary will notify the entity in writing when an investigation has been initiated. He will include in this notice a full statement of the pertinent facts and of the matters being investigated, and a statement that the entity may submit to him within 30 days from the date of the notice a written report concerning these matters. The Secretary will obtain any information he considers necessary to determine the issues and may employ site visits, public hearings, or any other procedures he considers appropriate to obtain this information.

(c) *Determinations and notifications by the Secretary.* (1) *Determinations.* On the basis of his investigation, the Secretary will determine whether the entity has failed to comply with any assurances it gave to the Secretary under this part. The Secretary will publish in the FEDERAL REGISTER a notice regarding each determination of noncompliance. In the case of a qualified HMO, a determination of noncompliance shall not affect its status as a qualified HMO, unless the Secretary makes the further determination described in paragraph (d)(1) of this section.

(2) *Notification of determination; corrective action.* The Secretary will notify the entity in writing of his determination. This notice shall specify the manner in which the entity has not complied with its assurances and shall direct the entity to initiate corrective action which the Secretary deems necessary to bring the entity into compliance. The entity shall initiate this corrective action within 30 days of the date on which the notice is issued by the Secretary or within any longer period which the Secretary determines to be reasonable and specifies in the notice. The entity shall carry out the corrective action within the period specified for that purpose by the Secretary. In the notice, the Secretary may provide the entity an opportunity to submit for his approval proposed methods for achieving compliance.

(d) *Remedies*—(1) *Qualified HMO's:* If the Secretary determines that a qualified HMO (A) has failed to initiate corrective action in accordance with paragraph (c)(2) of this section, or (B) has not carried out or refuses to carry out corrective action in accordance with paragraph (c)(2) of this section, the Secretary will, for purposes of section 1310 of the act, revoke the HMO's qualification and will notify the HMO of this action. The Secretary shall publish in the FEDERAL REGISTER each determination under this subparagraph. A revocation under this subparagraph shall have the effect described in § 110.905. Within 15 days after the date a notice of revocation is issued by the Secretary, the HMO shall, in a notice written in readily understandable language, describe the reasons for the determination that it is not a qualified HMO and shall send the notice to:

(i) The members of the HMO;

(ii) Each employer or public entity which has offered membership in the HMO in compliance with section 1310 of the act; and

(iii) Each lawfully recognized collective bargaining representative or other employee representative which represents the employees of the employer or public entity.

(2) *Other entities.* If, in the case of an entity which received a grant, loan, or loan guarantee under this part, the Secretary determines that it (A) has failed to initiate corrective action in accordance with paragraph (c)(2) of this section, or (B) has not carried out or refuses to carry out corrective action in accordance with paragraph (c)(2) of this section, he may, in addition to any other remedies available to him, bring a civil action in the United States district court for the district in which such entity is located to enforce its compliance with any assurances it furnished the Secretary respecting the provision of basic and supplemental health services or its organization or operation, as the case may be, which assurances were made in connection with its application under title XIII for the grant, loan, or loan guarantee.

(3) *Reimbursement of members for services improperly denied or for charges improperly imposed.* If, in the case of an HMO with respect to which a determination of non-compliance has been made under paragraph (c)(1) of this section the Secretary also finds that the HMO has failed to provide or arrange for health services for its members in accordance with assurances given by the HMO to him under this part, or that the HMO has provided health services but has charged the member in a manner inconsistent with these assurances, he may, in addition to the remedies listed in paragraph (d) (1) and (2) of this section, require the HMO to reimburse its members for the expenses of securing basic or supplemental health services which because of this noncompliance the members obtained other than through the HMO or for which it charged the member. The provisions of this subparagraph shall apply without regard to when the HMO failed to comply with the appropriate assurances.

### § 110.905 Effect of revocation of qualification for purposes of section 1310.

When an HMO's qualification is revoked under § 110.904(d)(1):

(a) The HMO may not seek inclusion in employees' health benefits plans under Subpart H of this part.

(b) With respect to employers including the HMO in the health benefits plan offered their employees, the HMO is not a qualified HMO for purposes of Subpart H of this part. Following the effective date of revocation, the inclusion of the health maintenance organization in an employees' health benefits plan will be disregarded for purposes of determining whether, and to what extent, the employer is subject to Subpart H of this part, and will not constitute compliance with the requirement of Subpart H of this part.

(c) The HMO is not a qualified HMO for purposes of the financial assistance programs under Subparts C, D, and E of this part until it is, in accordance with § 110.906, again qualified under subpart F of this part.

(d) The revocation of qualification shall be effective on the 5th working day after the HMO receives the notice.

### § 110.906 Reapplication for qualification.

An entity whose qualification as an HMO has been revoked by the Secretary for purposes of section 1310 of the act may, after completing the corrective action required under § 110.904(c)(2), reapply for a determination of qualification in accordance with the procedures specified in subpart F of this part.

### § 110.907 Waiver of assurances.

The Secretary may release an entity from compliance with any assurances given under this part for good cause shown, consistant with the purpose of title XIII of the act, except that upon the waiver of any assurance regarding the HMO's compliance with section 1301 of the act, the Secretary will revoke the qualification of the HMO unless the waiver is based on paragraph (c) of this section. Grounds upon which the Secretary will find good cause include, but are not limited to, the following:

(a) The entity has filed for reorganization under Federal bankruptcy provisions and the reorganization can only be approved with the waiver of the assurances;

(b) State laws governing the entity have been changed after it signed the assurances so as to prohibit the entity from being organized and operated in a manner consistent with the signed assurances, except to the extent that the changes would be superseded under the authority of section 1311 of the act; or

(c) Qualification requirements have been changed by a law of the United States.

federal register

Thursday
January 24, 1980

## Part IX

# Department of Health, Education, and Welfare

## Public Health Service

## Health Maintenance Organizations; Final Regulations Regarding Grants and Loan Guarantees

## DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

## Public Health Service

## 42 CFR Part 110

## Health Maintenance Organizations

**AGENCY:** Public Health Service, HEW.

**ACTION:** Final regulations.

**SUMMARY:** These rules amend the Public Health Service (PHS) regulations by implementing certain changes made by the HMO Amendments of 1978 with respect to grants and loan guarantees for planning and initial development costs (Subpart D) and to loans and loan guarantees for initial costs of operation (Subpart E). These regulations change Subpart D by including projects for the "expansion of services" of an HMO among the projects eligible for initial development assistance. In addition, they change the limits on the amount of assistance permitted for initial development projects. These regulations also change Subpart E by substituting the words "costs of operation" for the words "operating costs," thereby expanding the scope of assistance for initial operations (1) to include costs of certain small capital expenditures for equipment and alterations and renovations of facilities and (2) to incorporate into the regulations a long-standing policy which specifies the amount of preaward balance sheet liabilities which may be paid for with funds under operating loans (whether made directly or guaranteed by the Secretary).

**EFFECTIVE DATE:** These regulations are effective on January 24, 1980. However, comments are invited through March 24, 1980.

**FOR FURTHER INFORMATION CONTACT:** Howard R. Veit, Director, Office of Health Maintenance Organizations, Park Building—3rd Floor, 12420 Parklawn Drive, Rockville, Maryland 20857, 301-443-4106.

**ADDRESSES:** Interested persons are invited to submit written comments or suggestions on these rules to the person and office listed above. The comments will be available for public inspection and copying at the above address between the hours of 8:30 a.m. and 5:00 p.m., Monday through Friday, except for Federal holidays.

**SUPPLEMENTARY INFORMATION:** The Health Maintenance Organization Amendments of 1978 (Pub. L. 95-559) (the Amendments) revised and extended the provisions of Title XIII of the Public Health Service Act (the Act), as amended, to include, among other changes, provisions affecting grants and loan guarantees for planning and initial development of HMOs (section 1304 of the Act) and loans and loan guarantees for initial operating costs of HMOs (section 1305 of the Act). Final regulations to implement sections 1304 and 1305 of the Act were adopted in the **Federal Register** on October 27, 1978 (43 FR 50182-3, Subparts D and E). On February 22, 1979, certain amendments were made to Subpart E to conform to the HMO Amendments of 1978 (44 FR 10602-3). At that time, it was indicated that a number of other changes would be made in the regulations as a result of the Amendments. The regulations promulgated in this document make those changes and ones similarly needed for Subpart D.

For the reasons described below, the Secretary has determined that public participation in rulemaking prior to issuance of these regulations is unnecessary, impractical and contrary to public interest, and accordingly, that good cause exists for making these regulations effective on January 24, 1980.

With respect to Subpart D, the HMO Amendments of 1978 added projects for the "expansion of services" of an HMO to section 1304(b)(2) of the Act, which describes projects for which initial development assistance may be awarded. The revised Subpart B regulations, published in the **Federal Register** on July 18, 1979 (44 FR 42074-9), now provide a definition of "expansion of services" (§ 110.202) which can be used as a basis for awarding assistance under Subpart D. In addition, the Amendments increased the amount which may be awarded for initial development projects. A delay in the effective date would be detrimental to applicants for initial development assistance who need the increased award amounts and to HMOs which, in order to preserve or enhance their fiscally sound operation, urgently need financial support to expand their services.

With respect to Subpart E, the HMO Amendments of 1978 substituted, as a basis for assistance, the words "costs of operation" for the words "operating costs" in section 1305(a). In enacting this amendment, Congress authorized the Secretary to expand the scope of the costs that could be paid for with loan assistance under section 1305 of the Act. (See H.R. Rep. No. 95-1479, 95th Cong. 2nd Sess., Aug. 11, 1978, p. 58.) A delay in the effective date of Subpart E would be detrimental to HMOs which, in order to preserve or enhance their fiscally sound operation, urgently need the expanded basis for assistance to pay for the additional costs which may now be supported with loan assistance under section 1305.

Accordingly, the Secretary has determined that good cause exists for making these regulations effective upon publication. However, the Secretary invites public comments on these revisions and will consider them if received on or before March 24, 1980, in determining whether future revisions are appropriate. After the comment period, the Secretary intends to republish Subparts D and E in their entirety. The republication will take into account the comments received and will further simplify and clarify the regulations in accordance with the Department's Operation Common Sense.

The Secretary notes that the "costs of operation" which may now be supported under Subpart E are related only to the assistance provided under section 1305 of the Act. This term includes some costs which are characterized differently under the reimbursement principles of other programs administered by the Department, including the Medicare and Medicaid programs of Titles XVIII and XIX of the Social Security Act. As noted above, the broad definition of "costs of operation" under Subpart E implements a specific Congressional intent to provide assistance under section 1305 not only for "operating costs", as previously defined in the regulations, but also for certain small capital expenditures.

Set forth below is a summary of the amendments made in these regulations:

1. Sections 110.401(a), 110.402, and 110.404(f) are amended to include projects for the "expansion of services," as defined in § 110.202 of the revised subpart B regulations, among the projects eligible for initial development.

2. Section 110.405(b) is amended to delete any reference to dollar limitations for projects for initial development. Instead, reference is made to sections 1304(f)(2) and (f)(3) of the Act, which state respectively the amount authorized for any initial development project for an HMO and the cumulative total authorized for initial development projects for any HMO. This amendment permits the Secretary to implement the amendment to section 1304(f)(2), which increases the amount of initial development funds which may be awarded to an HMO for a particular project from a maximum of $1 million to $2 million effective October 1, 1979. These amendments will also facilitate the prompt implementation of any future legislative changes in the amounts authorized for initial development awards.

3. Section 110.405(b)(2) is amended to change the period for which an initial

development grant can be made from 1 year to 3 years, as provided by an amendment to section 1304(b)(3).

4. Section 110.405(b)(4) is revised by changing the reference from "§ 110.104(b)" to "§ 110.404(b)." The original reference was a typographical error.

5. The term "costs of operation" is substituted for "operating costs" and is defined to mean any cost incurred during the HMO's first 60 months of operation or expansion which:

a. Under generally accepted accounting principles or under accounting practices prescribed or permitted by State regulatory authority is not a capital cost;

b. Is required by State regulatory authority to meet reserve or tangible net equity requirements;

c. Is for a payment made to reduce balance sheet liabilities existing at the beginning of the 60 month period, but only if (i) the payment has been approved in writing by the Secretary and (ii) the total of these payments does not exceed 20 percent of the amount of the loan; or

d. Is for small capital expenditures (as defined in paragraph 6 below), but only if (i) this cost has been approved in writing by the Secretary, and (ii) the total of these costs does not exceed $200,000 in any 12 month period and $400,000 during the first 60 months of operation or expansion.

This definition covers those terms previously covered by the more limited operating costs definition (items a, b, and c), incorporates into the regulations the long-standing policy of the Department's Office of Health Maintenance Organizations as to the amount of balance sheet liabilities which may be covered by operating assistance (the limitations stated for item c) and adds language providing for payments from operating loan or loan guarantee funds for small capital expenditures (item d). The Secretary decided to impose the aggregate dollar limits on small capital expenditures in order to allow enough flexibility to cover the needs of HMOs, while insuring that sufficient funds would continue to be available to cover HMO operating deficits.

6. "Small capital expenditures" is defined in § 110.502(d) as expenditures for:

a. Equipment (as defined in 45 CFR Part 74.132, the Department's general regulation on grants administration); and

b. Alterations and renovations required to change the interior arrangements or other physical characteristics of an existing facility or installed equipment, so that it may be more effectively used for its currently designated purpose, or adapted to a changed use.

The Secretary has adopted definitions of equipment and alterations and renovations which are the same as those used in HEW grant programs in order to have uniform requirements for the various types of financial assistance available to HMOs. The limitation to "small" capital expenditures is consistent with the Congressional intent that major capital costs should be covered by the new Section 1305A authority for loans and loan guarantees for acquisition and construction of ambulatory facilities, rather than by funds for initial costs of operation. (See H.R. Rep. No. 95–1479, 95th Cong. 2nd. Sess., Aug. 11, 1978, p. 58.)

The Assistant Secretary for Health for the Department of Health, Education, and Welfare, with the approval of the Secretary of Health, Education, and Welfare, hereby amends 42 CFR Part 110, Subparts D and E, as set forth below.

(Sec. 215, 58 Stat. 690 (42 U.S.C. 216); secs. 1301–1318, as amended, 92 Stat. 2131–2141 (42 U.S.C. 300e–300e–17)).

Dated: September 28, 1979.

**Julius B. Richmond,**
*Assistant Secretary for Health.*

Approved: January 17, 1980.

**Patricia Roberts Harris,**
*Secretary.*

1. Section 110.401 is revised to read as follows:

### § 110.401 Applicability.

(a) The regulations of this subpart, in addition to the regulations of Subpart B of this part, apply to:

(1) Grants awarded under section 1304 of the Act for projects for the planning and for the initial development of HMOs.

(2) Guarantees made under section 1304 of the Act to non-Federal lenders of payment of the principal of and the interest on loans made for projects for the planning and initial development of HMOs.

(b)(1) Planning projects include projects for (i) the establishment of an HMO, and (ii) the significant expansion (as defined in § 110.202) of the membership or of the area served by an HMO.

(2) Initial development projects include projects for (i) the establishment of an HMO, (ii) the significant expansion (as defined in § 110.202) of the membership or of the area served by an HMO, and (iii) the expansion of the services (as defined in § 110.202) of an HMO.

2. Section 110.402 is revised to read as follows:

### § 110.402 Eligible applicants.

Any public entity or nonprofit private entity which is, or which proposes to become, an HMO is eligible to apply for a grant or a loan guarantee under this subpart. A for-profit private entity which is, or which proposes to become, an HMO is only eligible to apply for a loan guarantee under this subpart.

(a) In the case of a for-profit private entity, the applicant must demonstrate that at least 10 percent of the projected membership of the HMO to be established or expanded will be from medically underserved populations.

(b) Only HMOs qualified under Subpart F of this part are eligible to apply for projects for the significant expansion of their membership or of their service areas or for the expansion of their services.

### § 110.404 [Amended]

3. Section 110.404(f) is revised by deleting the word "significant" in the first sentence and by amending subparagraph (4) to read as follows:

* * * * *

(f) * * *

(4) The plans for the proposed expansion which demonstrate that the definition of "expansion of services" or of "significant expansion" of membership or service area in § 110.202 will be met.

### § 110.405 [Amended]

4. Section 110.405(b) is revised by amending subparagraphs (1) and (2) to read as follows:

* * * * *

(b) * * *

(1) The aggregate amount of loan guarantees and grants for any initial development project may not exceed the amount specified by section 1304(f)(2) of the Act. The cumulative total of grants made to and the principal of loans guaranteed for an HMO for initial development projects may not exceed the amount specified by section 1304(f)(3) of the Act.

(2) A grant may only be made for initial development costs incurred in a period not to exceed three years.

* * * * *

### § 110.405 [Amended]

5. Section 110.405(b)(4) is revised by changing the reference to "§ 110.104(b)" to read "§ 110.404(b)".

### § 110.502 [Amended]

6. Section 110.502(a) is revised to read as follows:

(a) "Costs of operation" means any cost incurred in the first 60 months of operation or expansion which:

(1) Under generally accepted accounting principles or under accounting practices prescribed or permitted by State regulatory authority is not a capital cost;

(2) Is required by State regulatory authority to meet reserved or tangible net equity requirements;

(3) Is for a payment made to reduce balance sheet liabilities existing at the beginning of the 60 month period, but only if (i) the payment has been approved in writing by the Secretary, and (ii) the total of these payments does not exceed 20 percent of the amount of the loan; or

(4) Is for a small capital expenditure, but only if (i) the cost has been approved in writing by the Secretary, and (ii) the total of these costs does not exceed $200,000 in any 12 month period and $400,000 during the first 60 months of operation or expansion.

* * * * *

### § 110.502 [Amended]

7. Section 110.502(d) is added, as follows:

* * * * *

(d) "Small capital expenditures" means expenditures for (1) equipment (as defined in 45 CFR 74.132); and (2) alterations and renovations required to change the interior arrangements or other physical characteristics of an existing facility or installed equipment, so that it may be more effectively used for its currently designated purpose, or adapted to a changed use.

### § 110.503 [Amended]

8. Section 110.503(b) is revised by replacing the words "operating costs", each time they appear, with the words "costs of operation".

### § 110.505 [Amended]

9. Section 110.505 is revised by replacing the words "operating costs" in the first sentence with the words "costs of operation".

### Subpart E [Title Amended]

10. The title of Subpart E is amended by replacing the words "operating costs" with the words "costs of operation".

[FR Doc. 80-2223 Filed 1-23-80; 8:45 am]

BILLING CODE 4110-85-M

federal register

Wednesday
April 9, 1980

## Part II

# Department of Health, Education, and Welfare

## Public Health Service

## Health Maintenance Organization Loans and Loan Guarantees for Acquisition and Construction of Ambulatory Health Care Facilities

## DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

### Public Health Service

### 42 CFR Part 110

### Health Maintenance Organization Loans and Loan Guarantees for Acquisition and Construction of Ambulatory Health Care Facilities

**AGENCY:** Public Health Service, HEW.

**ACTION:** Interim regulations.

**SUMMARY:** This notice sets forth the requirements for qualified health maintenance organizations (HMOs) to obtain loans or loan guarantees for the acquisition or construction of ambulatory health care facilities and the acquisition of equipment for those facilities. It also sets forth project requirements and procedures to be followed for repayment of the loan and in the event of a default. These rules implement Section 1305A of the Public Health Service Act, as amended.

**EFFECTIVE DATE:** These regulations are effective April 9, 1980. Comments are invited. To be considered, comments must be received by June 9, 1980.

**ADDRESS:** Written comments should be sent to the Director, Office of Health Maintenance Organizations, Office of the Assistant Secretary for Health, Park Building, 3rd Floor, 12420 Parklawn Drive, Rockville, Maryland 20857. The comments will be made available for public inspection and copying at the above address between the hours of 8:30 a.m. and 5:00 p.m., Monday through Friday, except for Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Howard R. Veit, Director, Office of Health Maintenance Organizations, Park Building, Room 3–10, 12420 Parklawn Drive, Rockville, Maryland 20857, 301/443–4106

**SUPPLEMENTARY INFORMATION:** The Health Maintenance Organization Amendments of 1978 (Pub. L. 95–559) revised and extended the provisions of Title XIII of the Public Health Service Act, as amended, to include, among other changes, a new Section 1305A, 42 U.S.C. 300e–4a, that provides for the Secretary to make and guarantee loans to qualified HMOs for the acquisition and construction of ambulatory health care facilities and for the acquisition of equipment for those facilities. With this authorization, the Secretary may make loan guarantees now without further legislation. However, until an appropriation act is enacted which contains authority to spend funds for direct loans, the Secretary may not make these loans. A delay in the publication of this subpart as final regulations would be detrimental to HMOs which, in order to preserve or enhance their fiscally sound operation, urgently need to acquire or construct ambulatory health care facilities. Since acquisition and construction may now be supported with loan guarantee assistance under Section 1305A, the Secretary has determined that notice and public comment on proposed rulemaking and further delay of the effective date would not be in the public interest and that good cause exists for making these regulations effective upon publication. Accordingly, these regulations are being published as interim regulations so that the Secretary may make loan guarantees authorized by Section 1305A as soon as possible. However, the Secretary invites public comments on these regulations and will consider them if received on or before June 9, 1980 in determining whether revisions are appropriate. After the comment period, the Secretary will revise the regulations, if warranted, in accordance with the comments received.

The Secretary directs attention to the following provisions of the regulations:

The statutory definition of "ambulatory health care facility," which is included in § 110.1002, specifies that diagnostic, treatment, and prevention services must all be provided in a facility if it is to be eligible for loan or loan guarantee assistance.

The statutory definition of "construction," which is also included in the definition section, provides that alteration, expansion, remodeling, renovation, and replacement, as well as new construction, are all eligible types of construction projects.

The definition of "equipment" in § 110.1002, together with an explicit statement in § 110.1008(b), makes clear that, in accordance with Section 1305A of the Act, loans may be made for the acquisition of equipment only if the equipment is for a facility acquired or constructed with assistance under this subpart.

As § 110.1003 states, only qualified public and nonprofit private HMOs are eligible for loan assistance under this subpart. For-profit qualified HMOs are eligible only for loan guarantees and only if 10 percent of the projected membership to be served by the facility to be acquired or constructed will be from a medically underserved population.

Section 110.1004, pertaining to application requirements, requires an applicant to submit additional information if a proposed transaction for which assistance is requested involves a party in interest (as defined in Section 1318 of the Act) or someone who will become a party in interest as a result of the transaction. The Secretary is concerned that parties in interest may participate in HMO management in a way which might be to the detriment of the HMO or its members. The Department is developing further guidance on the role of parties in interest in the management of all qualified HMOs. This guidance will be based on requirements applicable to all qualified HMOs: that they have fiscally sound operations and administrative and managerial arrangements satisfactory to the Secretary (Section 1301(c)(1) of the Act).

With respect to this ambulatory health care facility program, the possible involvement of parties in interest is addressed as follows. Where a party in interest is to be involved in a project for which assistance is requested, § 110.1004(c) requires that the application include the following:

(1) An explanation of the involvement of the party in interest;

(2) A combined financial statement for the HMO and the party in interest;

(3) A second appraisal (in addition to the one normally required) of property to be acquired from the party in interest;

(4) Evidence that each proposed transaction with a party in interest is consistent with prudent management and the fiscal soundness requirement in 42 CFR 110.108(a)(1); and

(5) Evidence that the transaction will not adversely affect the management decisions or fiscal soundness of , or the delivery of services by, the HMO. An example of the evidence which might satisfy this last requirement is a description of procedures which will prevent the party in interest from controlling the HMO's decisions with respect to the facility to be acquired or constructed with assistance under this subpart.

The Secretary will scrutinize this application information. Where she determines that the participation of a party in interest in a proposed transaction is likely to affect adversely the administration and fiscal soundness of the HMO or its delivery of health services, the Secretary will not award the requested loan or loan guarantee.

Section 110.1005 indicates that detailed plans which must satisfy the requirements of certain technical documents pertaining to construction standards, which are incorporated by reference, need not be submitted until an application has been approved. They must, however, be submitted before an approved loan is closed.

Section 110.1006 incorporates the statutory limit on the amount of loan assistance that may be provided for any single facility. This limit is presently $2,500,000 (see Section 1305A(b)(1) of the Act). To encourage the investment of private capital in HMOs, the regulations limit to 90 percent the percentage of project costs for which loans or loan guarantees will be made, although a greater percentage may be approved for good cause, as defined in the regulations.

The Secretary believes that the primary activity of an HMO should be the provision of basic health services as described in Subpart A of this part. Therefore, she believes that a facility acquired or constructed, in whole or in part, with assistance under this subpart should provide basic health services. The Secretary, consequently, has included in § 110.1007 a requirement that a facility acquired or constructed, in whole or in part, with assistance under this subpart must devote at least 50% of its useable space to the provision of basic health services.

Section 110.1007 also sets limits on the portion of a facility, acquired or constructed, in whole or in part, with assistance under this subpart, to be used for administrative functions and on the capacity of the assisted HMO. The maximum capacity of an assisted HMO (the capacity required to serve 110 percent of the projected HMO membership at the end of the 5 years following acquisition or completion of construction) has been established to prevent investment of Federal funds in idle capacity or in facilities which will not be used in the near future for the purpose for which the assistance is awarded. One hundred ten percent of the 5 year projection is permitted both to allow for actual variation from enrollment projections and to permit some services to patients on a fee-for-service basis where appropriate.

Similarly, where assistance is provided under this subpart for facilities to provide laboratory or X-ray services, the maximum capacity of all units of the HMO providing each assisted service is specifically limited to that needed to serve 110 percent of the projected number of HMO members at the end of 5 years. Where assistance is provided under this subpart for facilities to provide optical, pharmacy or dental services, a higher level (the capacity needed to provide the service to 200 percent of the projected number of HMO members for whom the service will be provided on a prepaid basis at the end of 5 years) is established as the maximum capacity for provision of each of the assisted services. The higher levels permit more flexibility with respect to these supplemental services, because projected use by HMO members alone is likely to be inadequate to make the service cost effective. In such cases, the additional capacity might be required to generate necessary fee-for-service revenue to cover service costs.

The restrictions in this section based on projected enrollments (paragraph (b)) apply to the total capacity of the HMO, including portions of the facility, if any, which are not acquired or constructed with assistance under this subpart and facilities, if any, which are located at other sites. The other requirements of this section (paragraph (a) (1) and (2)) apply only to an assisted facility (including portions not acquired or constructed with assistance under this subpart.)

In addition, provision is made for waiver or modification of any of these limitations on capacity for good cause. Good cause might include (a) changed circumstances during the 5 years following the completion of an acquisition or construction project or (b) the inaccessibility of certain services to a portion of the HMO membership.

Section 110.1008, regarding costs which are eligible for loan assistance under this subpart, indicates which costs are eligible with respect to leased property.

Sections 110.1009 through 110.1014 prescribe loan closing procedures and the required documents and terms for all loans or loan guarantees. Under § 110.1014, loans must be repaid over a period not to exceed the lesser of the useful life of the assisted facility or 25 years, except that the Secretary will approve shorter repayment periods where appropriate to the HMO's financial plan and where not inconsistent with the financial interest of the United States. Thus, because under § 110.1004(d), the applicant must give an assurance that it will have title to the facility for at least the repayment period, it usually will be required to have title for 25 years, unless the Secretary approves a shorter repayment period.

Section 110.1015 sets forth procedures to be followed in the event of a default on a guaranteed loan. Under this section, the Secretary may retain in the terms of a guarantee the option to direct the holder of the guaranteed loan to foreclose on its security in event of a default before the Secretary will pay amounts due under the guarantee.

The Assistant Secretary for Health for the Department of Health, Education, and Welfare, with the approval of the Secretary of Health, Education, and Welfare, hereby amends 42 CFR Part 110 by adding a new Subpart J, as set forth below.

Dated: January 11, 1980.

**Julius B. Richmond,**
*Assistant Secretary for Health.*

Approved: April 2, 1980.

**Patricia Roberts Harris,**
*Secretary.*

## Subpart J—Loans and Loan Guarantees for Acquisition and Construction of Ambulatory Health Care Facilities

Sec.

110.1001 To what loans and loan guarantees do these regulations apply?
110.1002 Definitions.
110.1003 What organizations are eligible for loans and loan guarantees?
110.1004 What are the requirements for an application?
110.1005 What information must be submitted by an applicant which has received a commitment for a loan to be made or guaranteed under this supbart before the closing of the loan?
110.1006 What are the limitations on loans and guaranteed loans?
110.1007 What requirements apply to projects assisted under this subpart?
110.1008 What is an eligible cost?
110.1009 What security is required?
110.1010 What evidence of indebtedness must be used?
110.1011 What legal opinions and documents must be furnished?
110.1012 How are loan closing dates determined?
110.1013 What interest must be paid by the borrower?
110.1014 How and over what period are loans and guaranteed loans to be repaid?
110.1015 What are the obligations and rights of the holder of the loan in the event of default on a guaranteed loan?
110.1016 On what basis may the Secretary waive rights of recovery?

**Authority:** Sec. 215 of the public Health Service Act, as amended, 58 Stat. 690 (42 U.S.C. 216); secs. 1301–1318 of the Public Health Service Act, as amended, 92 Stat. 2131–2141 (42 U.S.C. 300e–300e–17)

## Subpart J—Loans and Loan Guaranteees for Acquisition and Construction of Ambulatory Health Care Facilities

### § 110.1001 To what loans and loan guarantees do these regulations apply?

The regulations of this subpart, in addition to the regulations of Subpart B of this part, apply to loans and loan guarantees awarded to HMOs under section 1305A of the Public Health Service Act. These loans and loan guarantees are for projects for the acquisition of, the construction of, or the acquisition of equipment for, ambulatory health care facilities.

### § 110.1002 Definitions.

In addition to the terms defined in § 110.101 of this part:

"Ambulatory health care facility" or "facility" means a health care facility for the provision of diagnostic, treatment, and prevention services to ambulatory patients. If a facility occupies a portion of a building, the other parts of which are not owned by the HMO, the term does not include those other parts of the building. If an HMO is located in several buildings, each building in which the HMO provides diagnostic, treatment, and prevention services to ambulatory patients is a facility.

"Construction" means (a) the construction of new facilities; (b) the alteration, expansion, remodeling, replacement, and renovation of existing facilities; (c) off-site improvements in connection with an activity described in clause (a) or (b); and (d) the acquisition of land in connection with an activity described in clause (a), (b), or (c).

"Equipment" means those items which are necessary for the functioning of a facility acquired or constructed with a loan or loan guarantee awarded under this subpart, but does not include items of current operating expense such as food, fuel, pharmaceuticals, dressings, paper, printed forms and housekeeping supplies.

"Net assignable square footage" means the sum of all useable floor space measured on a floor plan to the inside faces of all enclosing walls or to lines denoting functional separations. Net assignable square footage includes all rooms to which a specific use can be assigned and excludes corridors, lobbies, toilets, mechanical shafts, ducts, electrical shafts or closets, elevators or elevators shafts, columns, exterior walls or partitions, service rooms, custodial supplies and general storage areas.

"Title" when used with reference to a facility which is proposed to be acquired or constructed with assistance under this subpart, means a fee simple or any other estate or interest (including a leasehold) which the Secretary finds sufficient to assure, for a period of not less than the repayment period of the loan to be made or guaranteed by the Secretary, undisturbed use and possession for the purposes of acquisition, or construction, and operation of the project.

### § 110.1003 What organizations are eligible for loans and loan guarantees?

(a) Any public health maintenance organization which is qualified under Subpart F of this part is eligible to apply for a loan under this subpart.

(b) Any nonprofit private health maintenance organization which is qualified under Subpart F of this part is eligible to apply for a loan or a loan guarantee under this subpart.

(c) Any private (other than a nonprofit private) health maintenance organization which is qualified under Subpart F of this part is eligible for a loan guarantee under this subpart, but only if it demonstrates that at least 10 percent of the members projected to be served in the facility to be acquired or constructed will be from medically underserved populations.

### § 110.1004 What are the requirements for an application?

(a) An applicant shall submit an application for a loan or loan guarantee to the Secretary at the time and in the form and manner that the Secretary prescribes.

(b) An application must contain an appraisal of the property to be acquired with a loan made or guaranteed under this subpart. The appraisal must be prepared by an independent appraiser approved in advance by the Secretary.

(c) (1) An application must identify any party in interest (as defined in § 110.101 of this part) with whom a transaction is proposed and for which transaction assistance is being requested under this subpart. The application must also identify any individual who would become a party in interest as a consequence of a proposed transaction.

(2) Where a party in interest is so identified, the application must include:

(i) An explanation of the involvement of the party in interest;

(ii) A combined financial statement for the HMO and the party in interest. This statement must be prepared by an independent auditor in accordance with generally accepted accounting principles with appropriate opinions and notes, and in the form and manner prescribed by the Secretary;

(iii) A second appraisal of property to be acquired from the party in interest. This second appraisal is in addition to that required under paragraph (b) of this section and must be prepared by another independent appraiser approved in advance by the Secretary;

(iv) Evidence that the cost of each proposed transaction with a party in interest is consistent with prudent management and the fiscal soundness requirements in 42 CFR 110.108(a)(1); and

(v) Evidence that the transaction will not adversely affect the management decisions or the fiscal soundness of the HMO. For example, a description of procedures which will prevent the party in interest from controlling decisions by the HMO will respect to the facility to be constructed or acquired under this subpart would meet this requirement.

(3) The Secretary will disapprove an application where he or she determines that the participation of a party in interest is likely to affect adversely the administration and fiscal soundness of the HMO or its delivery of health services.

(d) An application must include an assurance satisfactory to the Secretary that the HMO will have title (as defined in § 110.1002) to the facility.

(e) An application must include an assurance satisfactory to the Secretary that the HMO will continue to comply with the restrictions on capacity set out in § 110.1007(b) for the five years following completion of acquisition or construction.

(f) An application must include line drawings of the proposed facility demonstrating that the allocation of square footage complies with the requirements of § 110.1007.

(g) The application must be executed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the statute, the regulations of this part, and the terms of the loan documents and the loan guarantee, if any.

### § 110.1005 What information must be submitted by an applicant which has received a commitment for a loan to be made or guaranteed under this subpart before the closing of the loan?

(a) Design, bid, and contract documents for each project must be prepared in accordance with all of Part 2.1 (except sections 5.4, 8.8, 11.2, 11.3, 11.4, Chapter 12, sections 13.2, 13.3 and Exhibits 9 and 10) of DHEW *Technical Handbook for Facilities Engineering and Construction Manual, Federally Assisted Construction*, entitled "2.1 Information for Project Applicants and State Agencies on Design and Construction Related Activities." With these exceptions, Part 2.1 is incorporated into this subpart by reference. This part of the Handbook will be provided to all applicants and is available at cost to any interested person upon request to the Office of Health Maintenance Organizations in any of the Department's Regional Offices. The addresses of Regional Offices are listed in 45 CFR 5.31(b). This part of the Handbook is also available for inspection without charge at these offices. If this handbook is amended, a notice of the amendments will be published in the **Federal Register** and a copy of the amendments will be on file at the Office of the Federal Register. The design, bid, and contract documents must be submitted to the Secretary for approval before the closing of a loan to be made or guaranteed under this subpart.

(b) The plans and specifications for the design and construction of, and equipment for, a facility submitted to the Secretary must conform with:

(1) State and local codes, laws, and ordinances, and

(2) Chapter 14 of DHEW Publication No. (HRA) 79-14500, *Minimum Requirements of Construction and Equipment for Hospitals and Medical Facilities,* "Small Primary Health Care Centers," except for the last sentence of paragraph 14.1A, the parenthetical phrase "(usually 4)" in paragraph 14.1B(1) and paragraph 14.1B(3) in its entirety. With these three exceptions, Chapter 14 of this document is incorporated into this subpart by reference. This publication will be provided to all applicants and is available for the cost of reproduction to any interested person upon request to the Office of Health Maintenance Organizations in any of the Department's Regional Offices. The addresses of Regional Offices are listed in 45 CFR 5.31(b). This publication is also available for inspection without charge at these offices. If this publication is amended, a notice of the amendments will be published in the **Federal Register** and a copy of the amendments will be on file at the Office of the Federal Register.

Incorporation by reference provisions approved by the Acting Director of the Federal Register on October 22, 1979.

### § 110.1006 What are the limitations on loans and guaranteed loans?

(a) The aggregate amount of principal of loans made or guaranteed, or both, for an ambulatory health care facility under this subpart may not exceed the amount specified by section 1305A(b)(1) of the Act.

(b) The aggregate amount of loans made or guaranteed under this subpart for a project may not exceed 90 percent of the eligible costs of the project unless the Secretary, for good cause, approves a greater percentage.

(1) In determining whether there is good cause for approving a greater percentage, the Secretary will consider:

(i) The availability of other sources of funds to the applicant;

(ii) The effect on the security for the loan of other borrowing by the applicant to pay for the remainder of the project costs; and

(iii) Any other factors the Secretary determines are consistent with the purposes of the Act.

(2) The applicant may not use any funds provided under other subjects of this part to pay for any portion of the project costs not paid for by the loan made or guaranteed under this subpart.

### § 110.1007 What requirements apply to projects assisted under this subpart?

Projects assisted or to be assisted under this subpart must comply with the following requirements, unless a requirement is waived or modified by the Secretary for good cause.

(a) *Net assignable square footage limitations applicable to a facility.* The following limitations apply to an assisted facility, including any portion of the facility acquired or constructed (or to be acquired or constructed prior to the termination of the 5-year period following acquisition or construction) without Federal assistance under this subpart:

(1) Not more than 25 percent of the net assignable square footage (as defined in 110.1002) may be devoted to administrative functions of the HMO. The remainder must be devoted to clinical use. For the purpose of this paragraph, (i) administrative functions include general administration, marketing, enrollment and claims processing, and (ii) clinical uses of space include medical records storage, clinical administration, and space for the provision of basic health services, health education, and pharmacy, optical, dental, laboratory, X-ray, and other health services.

(2) At least 50 percent of the net assignable square footage must be for the provision of basic health services (as defined in Subpart A of this part).

(b) *Net assignable square footage limitations applicable to an HMO.* The following limitations apply to the net assignable square footage of all the facilities to be available to the HMO during the five year period following the completion of the acquisition or construction to be assisted under this subpart. This includes any net assignable square footage available or to be available to the HMO for the purposes specified below, whether or not acquired or constructed with assistance under this subpart:

(1) The net assignable square footage available to the HMO may not exceed that needed to serve 110 percent of the projected number of HMO members at the end of the 5 year period after the acquisition or construction is to be completed. The applicant shall calculate the amount of net assignable square footage which is needed in accordance with instructions provided by the Secretary.

(2) Where assistance under this subpart is used to acquire or construct facilities for the provision of optical, pharmacy or dental services, the total net assignable square footage available to the HMO for the provision of each of these assisted services may not exceed that needed to serve 200 percent of the projected number of HMO members at the end of the 5-year period after the acquisition or construction is to be completed. Only the HMO members projected to be enrolled to receive these services on a prepaid basis may be counted for purposes of this limitation. The applicant shall calculate the amount of net assignable square footage which is needed in accordance with instructions provided by the Secretary.

(3) Where assistance under this subpart is used to acquire or construct facilities for the provision of laboratory or X-ray services, the total net assignable square footage available to the HMO for the provision of each of these assisted services may not exceed that needed to serve 110 percent of the projected number of HMO members at the end of the 5 year period after the acquisition or construction is to be completed. The applicant shall calculate the amount of net assignable square footage which is needed in accordance with instructions provided by the Secretary.

### § 110.1008 What is an eligible cost?

(a) The Secretary will consider only eligible costs in determining the amount of a loan to be made or guaranteed under this subpart. Eligible costs are those which are reasonable and necessary for the acquisition or construction of, or the purchase of equipment for, a facility or portion of a facility. Costs which the Secretary determines to be inappropriate to the needs of a particular HMO and other costs which the Secretary specifies in materials to be provided to each applicant are not eligible costs.

(b) The cost of acquisition of equipment is an eligible cost only if the equipment is for a facility acquired or constructed, or to be acquired or constructed, with a loan made or guaranteed under this subpart.

(c) Acquisition of land for a facility is an eligible cost only if it is in connection with the acquisition or construction of a facility on that land.

(d) The costs of leasing land, a facility, or equipment for a facility are not eligible costs. The costs of construction on leased land, including renovation of a leased facility, may be eligible costs if adequate security is available to protect the financial interests of the United States.

(e) The cost of repaying an interim construction loan for a facility is an eligible cost.

### § 110.1009 What security is required?

All loans and guaranteed loans shall be secured in a manner which the Secretary finds sufficient to ensure repayment and to protect the financial interests of the United States. The Secretary will file or require the filing of all documents necessary to perfect the security interests of the United States.

### § 110.1010 What evidence of indebtedness must be used?

The evidence of indebtedness with respect to loans made or guaranteed under this supart shall be in the form of a debt instrument which is acceptable to the Secretary.

### § 110.1011 What legal opinions and documents must be furnished?

At appropriate stages in the application and loan closing process, the applicant, at the request of the Secretary, shall furnish opinions by legal counsel who is acceptable to the Secretary, in the form and manner prescribed by the Secretary.

### § 110.1012 How are loan closing dates determined?

(a) *Loans.* Closing for any loan by the Secretary under this subpart shall be accomplished at a time determined by the Secretary.

(b) *Loan Guarantees.* Closing for any loan for which a guarantee is made under this subpart shall be accomplished at a time agreed upon by the parties to the loan and the Secretary.

### § 110.1013 What interest must be paid by the borrower?

(a) Each loan made by the Secretary shall bear interest at a rate determined by the Secretary.

(b) Each loan guaranteed by the Secretary shall bear interest at a rate approved by the Secretary.

### § 110.1014 How and over what period are loans and guaranteed loans to be repaid?

(a) The principal amount of each loan or guaranteed loan, together with interest thereon, must be repayable in accordance with a repayment schedule which is to be agreed upon by the parties to the loan, or by the parties to the guaranteed loan and the Secretary, prior to or at the time of the closing of the loan. Unless otherwise authorized by the Secretary, each loan made or guaranteed by the Secretary must be repayable in substantially level installments of interest and principal (except as provided in paragraph (b) of this section) sufficient to amortize the loan through the final year of the life of the loan.

(b) Interest on the unpaid principal amount of the loan shall be due and payable not less frequently than semi-annually from the date of the initial disbursement of funds under the loan. Principal repayments shall be paid not less frequently than semi-annually but may be deferred until completion of the project.

(c) Each loan or guaranteed loan shall be repayable over a period approved by the Secretary, not to exceed 25 years beginning on the date of closing of the loan.

(1) The Secretary may approve a repayment period of less than 25 years in particular cases if he or she determines that a shorter repayment period is more appropriate to an applicant's total financial plan and not inconsistent with the financial interests of the United States.

(2) A loan repayment period may not exceed the estimated useful life of the facility to be acquired or constructed with the assistance of the loan. In the case of a loan solely for acquisition of equipment for a facility previously assisted under this subpart, the loan repayment period may not exceed the estimated useful life of the most expensive items of equipment.

(3) Where a leased facility is being constructed (i.e., renovated) with assistance under this subpart, or a facility is being acquired or constructed on leased land with assistance under this part, the loan repayment period may not be longer than the period of the lease.

### § 110.1015 What are the obligations and rights of the holder of the loan in the event of a default on a guaranteed loan?

When the holder of a loan guaranteed by the Secretary under this subpart is the Federal Financing Bank, the obligations and rights of the holder in the event of default will be set forth in the loan documents and in the terms of the guarantee. For other holders, the procedures to be followed in the event of default are set forth below:

(a) If a borrower defaults on a loan guaranteed by the Secretary under this subpart, the holder of the loan shall promptly give the Secretary written notification of this default. The Secretary will, immediately upon receipt of the notice, provide the holder with written acknowledgement of its receipt.

(b) If a default in making periodic payment of the principal and interest on the guaranteed loan is not cured within 90 days after receipt by the Secretary of notice of the default, the holder of the loan shall have the right to make written demand upon the Secretary for payment under the guarantee. Upon receiving this demand, the Secretary will, at his or her option, either:

(1) Pay to the holder of the loan the full amount of all overdue payments (principal, accrued interest, and reasonable late charges if assessed in the form of additional interest) and continue to make payments on the loan when due until the applicant resumes making payments or until the Secretary elects either to purchase the loan under subparagraph (2) or to make payments under subparagraph (3); or

(2) Purchase the loan through the payment to the holder of the full unpaid principal amount together with accrued interest and reasonable late charges (if assessed in the form of additional interest) imposed in accordance with the instrument evidencing or securing the loan; or

(3) Direct the holder to foreclose upon and dispose of the security for the loan (as provided in the security instrument), if the Secretary has reserved the right so to direct the holder under the terms of the loan guarantee. After the foreclosure and disposition, the Secretary will pay to the holder the outstanding balance of the loan (principal, accrued interest, and reasonable late charges if assessed in the form of additional interest) less the net proceeds of the foreclosure and disposition.

(c) If the borrower fails to cure a default on the loan (other than a default in the payment of principal and interest) within 90 days after the Secretary receives the notice of the default, the holder of the laon shall have the right to accelerate payment of the loan.

(1) If the borrower cannot make this payment, the holder may make written demand upon the Secretary for payment under the guarantee.

(2) The Secretary will, upon receiving this written demand; either

(i) Purchase the loan through the payment to the holder of the full unpaid principal amount together with accrued interest and reasonable late charges (if assessed in the form of additional interest) imposed in accordance with the instrument evidencing or securing the loan; or

(ii) Direct the holder to foreclose upon and dispose of the security for the loan (as provided in the security instrument), if the Secretary has reserved the right so to direct the holder under the terms of the loan guarantee. After the foreclosure and disposition, the Secretary will pay to the holder the outstanding balance of the loan (principal, accrued interest, and reasonable late charges if assessed in the form of additional interest) less the net proceeds of the foreclosure and disposition.

### § 110.1016 On what basis may the Secretary waive rights of recovery?

In determining whether there is good cause for waiver of any right of recovery which the Secretary may have against an HMO, either because of a loan made under this subpart or because of a payment made under a loan guarantee under this subpart, he or she will take into consideration the extent to which:

(a) The recipient of the loan or guaranteed loan or other owner of the facility with respect to which the loan or loan guarantee was made will continue to use it for (1) the purpose for which it was constructed or (2) another public or nonprofit purpose which will promote the purposes of the Act;

(b) There are reasonable assurances that for the remainder of the repayment period of the loan, other public or nonprofit facilities not previously used for the purpose for which the facility was constructed will be so used and are substantially equivalent in nature and extent for that purpose;

(c) The recovery would seriously curtail the provision of medical services to persons in need of these services in the area; and

(d) It is likely that payment can be obtained which would be greater than the costs the government would incur as a result of continuing to pursue collection.

[FR Doc. 80-10506 Filed 4-8-80; 8:45 am]

BILLING CODE 4110-85-M

# HMO Disclosure

June 22, 1979

(4) That requests for the materials described in paragraph (b)(3) of this section may be addressed to the plan administrator.

2. Amend § 2520.104–20 by amending paragraph (b)(2)(ii) thereof to read as follows:

**§ 2520.104–20 Limited exemption for certain small welfare plans.**

* * * * *

(b) * * *

* * * * *

(2) * * *

(ii) the benefits of which are provided exclusively through insurance contracts or policies issued by an insurance company or similar organization which is qualified to do business in any State or through a qualified health maintenance organization as defined in section 1310(d) of the Public Health Services Act, as amended, 42 U.S.C. 300e–9(d), the premiums for which are paid directly by the employer or employee organization from its general assets or partly from its general assets and partly from contributions by its employees or members, *Provided*, that contributions by participants are forwarded by the employer or employee organization within three months of receipt, or

* * * * *

3. Amend § 2520.104–44 by amending paragraph (b)(1)(ii) thereof to read as follows:

**§ 2520.104–44 Limited exemption and alternative method of compliance for annual reporting by unfunded plans and by certain insured plans.**

* * * * *

(b) *Application.* * * *

(1) * * *

* * * * *

(ii) The benefits of which are provided exclusively through insurance contracts or policies issued by an insurance company or similar organization which is qualified to do business in any State or through a qualified health maintenance organization as defined in section 1310(d) of the Public Health Services Act, as amended, 42 U.S.C. 300e–9(d), the premiums for which are paid directly by the employer or employee organization from its general assets or partly from its general assets and partly from contributions by its employees or members, provided that any plan assets held by such an insurance company are held solely in the general account of such company, contributions by participants are forwarded by the employer or employee organization within three months of receipt and, in the case of a plan that provides for the return of refunds to contributing participants, such refunds are returned to them within three months of receipt by the employer or employee organization, or

* * * * *

## PART 2560—RULES AND REGULATIONS FOR ADMINISTRATION AND ENFORCEMENT

4. Amend § 2560.503–1 by revising paragraph (b)(1)(i) thereof and adding thereto a new paragraph (j), to read as follows:

**§ 2560.503–1 Claims procedure.**

* * * * *

(b) *Obligation to establish* * * *

(1) * * *

(i) Complies with the provisions of paragraphs (d) through (h) of this section, except to the extent that it is deemed to comply with some or all of such provisions under the authority of paragraph (b)(2) or paragraph (j) of this section.

* * * * *

(j) *Qualified Health Maintenance Organizations.* Claims procedures with respect to any benefits provided through membership in a qualified health maintenance organization, as defined in section 1310(d) of the Public Health Services Act, as amended, 42 U.S.C. 300e–9(d), established by such qualified health maintenance organization in conformity with the requirements of section 1301 of the Public Health Services Act, as amended, 42 U.S.C. 300e, and the regulations thereunder shall be deemed to satisfy the requirements of section 503 of the Act and of this section with respect to the provision of such benefits to persons who are members of such qualified health maintenance organization.

Signed at Washington, D.C., this 8th day of June, 1979.

**Ian D. Lanoff,**

*Administrator, Pension and Welfare Benefit Programs, Labor-Management Services Administration.*

[FR Doc. 79-19444 Filed 6-21-79; 8:45 am]

BILLING CODE 4510-29-M

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## DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

### Public Health Service

### [42 CFR Part 110]

## Health Maintenance Organizations; Requirements

**AGENCY:** Public Health Service, HEW.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This notice sets forth proposed amendments to the requirements for the operation of health maintenance organizations (HMOs). These requirements relate to the disclosure of information by HMOs to members, potential members, and employers. These amendments are proposed to coordinate with requirements under the Employee Retirement Income Security Act of 1974 (ERISA). Interested parties are invited to submit written comments and suggestions concerning the proposed amendments.

**DATE:** Comments must be received by August 21, 1979.

**ADDRESSES:** Written comments should be sent to the Director, Office of Health Maintenance Organizations, Office of the Assistant Secretary for Health, Park Building, 3rd Floor, 12420 Parklawn Drive, Rockville, Maryland 20857. The comments will be available for public inspection and copying at the above address between the hours of 8:30 a.m. and 5:00 p.m., Monday through Friday, except for Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Howard R. Veit, Director, Office of Health Maintenance Organizations, Park Building, 3rd Floor, 12420 Parklawn Drive, Rockville, Maryland 20857, 301/443–4106.

**SUPPLEMENTARY INFORMATION:** 42 CFR 110.108(c) requires that HMOs qualified under Title XIII of the Public Health Service Act offer enrollment to various categories of persons residing in their service areas, and that they do so after "full and fair disclosure" of certain aspects of their organization and operation. It is proposed that the disclosure provisions of § 110.108(c) be amended to include certain of the basic disclosure items and information required by the Department of Labor in its implementation of the Employee Retirement Income Security Act of 1974 ("ERISA"). Section 110.108(c) would also be expanded to include information on the financial condition of HMOs. The proposed amendment to the "full and fair disclosure" requirements of § 110.108(c) also provides that the written descriptions required of HMOs are to be written so that they can be easily understood by the average person considering enrollment in an HMO.

In addition, a new paragraph (s) is proposed to be added to § 110.108. This paragraph would require that a qualified HMO provide to each employer or designee offering the HMO option to its employees those informational materials which it requests and which are necessary to satisfy its reporting and disclosure obligations under ERISA insofar as that HMO is concerned.

These proposed regulations are being published simultaneously with proposed regulations issued by the Department of Labor which would, among other things, provide certain exemptions from the disclosure requirements of ERISA (see 29 CFR 2520.102-3). If both the regulations proposed by the Department of Health, Education, and Welfare and those proposed by the Department of Labor are adopted, certain of the information supplied by HMOs under the HEW regulations will in effect serve as a substitute for information which ERISA would otherwise require to be supplied by administrators of employee benefit plans under which membership in a qualified HMO is an available benefit. Specifically, a substantial portion of the materials which would be required to be submitted in the summary plan description required by section 102 of ERISA could be omitted. The Department of Labor's proposed regulations would also make clear that plans would not be required to have claims procedures duplicating those established by qualified HMOs.

The Assistant Secretary for Health of the Department of Health, Education, and Welfare, with the approval of the Secretary of Health, Education, and Welfare, proposes to revise 42 CFR § 110.108 as set forth below.

Dated: May 10, 1979.

**Charles Miller,**

*Acting Assistant Secretary for Health.*

Approved: May 24, 1979.

**Joseph A. Califano, Jr.,**

*Secretary.*

(Sec. 215, 58 Stat. 690 (42 U.S.C. 216); secs. 1301-1318, as amended, 92 Stat. 2131-2141 (42 U.S.C. 300e-300e-17))

## PART 110—HEALTH MAINTENANCE ORGANIZATIONS

1. In § 110.108, paragraph (c) is revised and a new paragraph (5) is added to read as follows:

### § 110.108 Organization and operation.

* * * * *

(c)(1) *Full and fair disclosure.* Prepare a written description of its benefits (including limitations and exclusions), coverage (including a statement of conditions on eligibility for benefits), procedures to be followed in obtaining benefits, circumstances under which benefits may be denied, rates, grievance procedures, service area, location, hours of service, and a general description of participating providers and the financial condition of the HMO. This description shall be written so that it can be easily understood by the average person who might enroll in the HMO. The description of coverage and benefits may be in general terms if reference is made to a detailed statement of coverage and benefits which is available without cost to any person to whom the opportunity for enrollment in the HMO is offered or who has enrolled in the HMO. Upon request made directly to the HMO or to the plan administrator (as that term is defined under the Employee Retirement Income Security Act of 1974, "ERISA") of a health benefits plan which includes the HMO option, the HMO shall provide the description to any person who is a participant or beneficiary of the plan and who is eligible to elect the HMO option.

(2) *Broadly representative enrollment.* After providing the written description referred to in paragraph (c)(1) of this section, offer enrollment to persons who are broadly representative of the various age, social, and income groups within its service area. In the case of an HMO which has a medically underserved population located in its service area, not more than 75 percent of the HMO members may be enrolled from the medically underserved population unless the area in which that population resides is also a rural area.

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(5) *Reporting and Disclosure under ERISA.* Provide each employer or designee (as those terms are defined in § 110.801 of this Part) or plan adminstrator (as that term is defined under the Employee Retirement Income Security Act of 1974, "ERISA") including the HMO option in its employees' health benefits plan, upon request, the information which is necessary to satisfy its reporting and disclosure obligations under ERISA insofar as that HMO is involved.

[FR Doc. 79-19445 Filed 6-21-79; 8:45 am]

BILLING CODE 4110-85-M

# SECTION IV

## Interpretive Rulings

## PHS/OHMO - § 110.101 Definitions - health maintenance organization

> "Health maintenance organization" (HMO) means a legal entity which provides or arranges for the provision of basic and supplemental health services to its members in the manner prescribed by, is organized and operated in the manner prescribed by, and otherwise meets the requirements of, section 1301 of the Act and the regulations of this subpart.

Q. Is it permissible for an HMO to be a cost center or separate line of business of a sponsoring organization (i.e., the organization which provides initial financing or in-kind contributions or controls the policies and the operations of the HMO)?

A. No. The HMO must be a separate legal entity with its own policymaking body. Therefore, it is not permissible for an HMO to be a cost center or separate line of business of a sponsoring organization. However, administration of the HMO may be through a designated unit or cost center of a legal entity, if the legal entity is the HMO.

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Q. Is it permissible for an HMO to be a subsidiary of a sponsoring organization?

A. Yes. An HMO may be a subsidiary if the HMO itself is a legal entity meeting the requirements of Title XIII.

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Q. Is it permissible for an HMO to share a license to operate with a sponsoring organization?

A. No. The HMO must be a separate legal entity holding its own license to operate, if such a license is required by state law.

## PHS/OHMO - § 110.101 Definitions - individual practice association

"Individual practice association" (IPA) means a partnership, association, corporation, or other legal entity:

(1) Which delivers or arranges for the delivery of health services and which has entered into a written services arrangement or arrangements with health professionals, a majority of whom are licensed to practice medicine or osteopathy. The written services arrangement shall provide:

(i) That these health professionals shall provide their professional services in accordance with a compensation arrangement established by the entity; and

(ii) To the extent feasible:

(A) For the sharing by these health professionals of health (including medical) and other records, equipment, and professional, technical, and administrative staff; and

(B) For the arrangement and encouragement of the continuing education of these health professionals in the field of clinical medicine and related areas.

Q. Are there any limitations on the IPA's activities with respect to its non-HMO patients?

A. Not under Title XIII.

## PHS/OHMO - § 110.101 Definitions - medical group

"Medical group" means a partnership, association, corporation, or other group:

(1) Which is composed of health professionals licensed to practice medicine or osteopathy and of such other licensed health professionals (including dentists, optometrists, and podiatrists) as are necessary for the provision of health services for which the group is responsible;

(2) A majority of the members of which are licensed to practice medicine or osteopathy; and

(3) The members of which:

(i) As their principal professional activity (over 50 percent individually) engage in the coordinated practice of their profession and as a group responsibility have substantial resonsibility (over 35 percent in the aggregate of their professional activity) for the delivery of health services to members of an HMO;

(ii) Pool their income from practice as members of the group and distribute it among themselves according to a prearranged salary or drawing account or other similar plan unrelated to the provision of specific health services;

(iii) Share health (including medical) records and substantial portions of major equipment and of professional, technical, and administrative staff;

(iv) Arrange for and encourage continuing education in the field of clinical medicine and related areas for the members of the group and helath professionals employed by the group; and

(v)Establish an arrangement whereby a member's enrollment status is not known to the health professional who provides health services to the member.

Q. Is the principal professional activity requirement (over 50 percent individually) limited to direct patient care?

A. No. The over 50 percent requirement applicable to each individual refers to his or her commitment to the medical group and may include related activities, such as teaching or research.

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Q. Within the first four years after qualification, may a health professional who devotes 50 percent or less of his professional activity to the coordinated practice of his profession be a member of the medical group with which an HMO contracts?

A. Yes.

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Q. Four years after the HMO's qualification, may a health professional who devotes 50 percent or less of his professional activity to the coordinated practice of his profession be a member of the medical group with which an HMO contracts?

A. No. Section 110.104(a)(3) requires that four years after qualification the HMO not contract with a medical group unless each member of the medical group devotes at least 50 percent of his principal professional activity to the coordinated practice of his profession.

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Q. Must the professional activities in which the coordinated practice of a health professional takes place be for a single medical group?

A. Yes. This definition of medical group applies to a single medical group affiliated with an HMO.

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continued on next page ...

## PHS/OHMO - § 110.101 Definitions - medical group (continued)

"Medical group" means a partnership, association, corporation, or other group:

(1) Which is composed of health professionals licensed to practice medicine or osteopathy and of such other licensed health professionals (including dentists, optometrists, and podiatrists) as are necessary for the provision of health services for which the group is responsible;

(2) A majority of the members of which are licensed to practice medicine or osteopathy; and

(3) The members of which:

(i) As their principal professional activity (over 50 percent individually) engage in the coordinated practice of their profession and as a group responsibility have substantial resonsibility (over 35 percent in the aggregate of their professional activity) for the delivery of health services to members of an HMO;

(ii) Pool their income from practice as members of the group and distribute it among themselves according to a prearranged salary or drawing account or other similar plan unrelated to the provision of specific health services;

(iii) Share health (including medical) records and substantial portions of major equipment and of professional, technical, and administrative staff;

(iv) Arrange for and encourage continuing education in the field of clinical medicine and related areas for the members of the group and helath professionals employed by the group; and

(v)Establish an arrangement whereby a member's enrollment status is not known to the health professional who provides health services to the member.

Q. Must the substantial responsibility requirement of the group relate to a single HMO?

A. Yes. The requirement that the group have substantial responsibility for the delivery of health services to members of an HMO refers to members of a single HMO.

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Q. Does the principal professional activity requirement apply to health professionals associated with an IPA or staff model HMO?

A. No. The requirement is applicable only to the medical group model HMO.

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Q. Are there any limitations on the medical group's activities with respect to its non-HMO patients?

A. Not under Title XIII.

## PHS/OHMO - § 110.101 Definitions - medical group member

> "Medical group member" means (1) a health professional engaged as a partner, associate, or shareholder in the medical group, or (2) any other health professional employed by the group who may be designated as a medical group member by the medical group.

Q. May a health professional associated with a medical group be exempt from the principal professional activity requirement?

A. Yes. A health professional who is neither a partner, associate, or shareholder in a medical group, nor designated "a medical group member" by the partners, associates, or shareholders, is exempt from the principal professional activity requirement.

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Q. May a health professional associated with a medical group be exempt from the calculations regarding the 35 percent of the group's responsibilities toward HMO members?

A. Yes. A health professional who is not a "member" as defined above is excluded from the calculations regarding the 35 percent responsibilities toward HMO members.

## PHS/OHMO - § 110.101 Definitions - medically underserved population

> "Medically underserved population" means the population of an urban or rural area designated by the Secretary as an area with a shortage of personal health services. The Secretary will designate these areas as described in § 110.203(d).

Q. What are the criteria which the Secretary uses to determine if an area is medically underserved?

A. As described in Section 110.203(d), medically underserved areas are designated by the Secretary taking into consideration at least the following factors:

1. Ratio of primary care physicians to population;
2. Infant mortality rate;
3. Percentage of the population which is age 65 or over; and
4. Percentage of the population with family income below the poverty level.

A list of medically underserved areas already designated may be obtained by writing the Regional Health Administrator in the appropriate Regional Office of the Department of Health, Education, and Welfare at the addresses set forth at 45 CFR 5.31(b).

It should be noted that for the purposes of determining whether an HMO is required to have representation of a medically underserved population on the policymaking body (Section 110.108(h)(1)(ii)), such determination shall be made on the basis of the percentage of the HMO's enrollment residing in areas which have been designated as medically underserved areas.

## PHS/OHMO - § 110.101 Definitions - subscriber

"Subscriber" means a member who has entered into a contractual relationship with the HMO or who is responsible for making payments for basic health services (and contracted for supplemental health services) to the HMO or on whose behalf these payments are made.

Q. May an HMO contract with an other party which issues to the subscriber, on behalf of the HMO, a contract for HMO membership?

A. Yes.

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Q. Are there conditions governing an other party-subscriber contract?

A. Yes. The subscriber contract issued by an other party must:

1. Conform with the benefit and payment requirements of the Act;
2. Specify that the HMO has the ultimate responsibility to provide or arrange for and be responsible for the delivery of all contracted for services; and
3. Specify that in the event the HMO's contract with the other party terminates, the HMO is obligated to continue to provide or arrange for services to which members are entitled under the subscriber contract.

> **§ 110.102 Health benefits plan: basic health services.**
>
> (a) An HMO shall provide or arrange for the provision of basic health services to its members as needed and without limitations as to time and cost other than those prescribed in the Act and these regulations, as follows:

Q. Who determines whether basic health services are medically necessary?

A. The HMO, through its providers, makes the determination on a case-by-case basis as to which basic (and supplemental services, if offered) are medically necessary services to be provided to members.

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Q. If a member is hospitalized on the effective date of group coverage, is the HMO responsible for the provision of medically necessary basic health services for that member?

A. Yes. So long as the member agrees to come under the care of the HMO, the HMO is responsible for providing health services to that member.

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Q. Are ambulance services a basic health service?

A. Yes. Ambulance services determined to be medically necessary are required basic health services. (See Section 110.102(d)(5) for the exclusion of non-medically necessary ambulance services.)

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Q. Is it allowable for a multi-site HMO to require a member to designate one specific site of the HMO within the service area from which the member is to receive most basic health services?

A. Yes. However, an HMO may not deny a member a medically necessary service sought at a different site of the HMO than the one the member designated, if its provision is immediately required. Further, the HMO may not insure or make other arrangements for the costs of providing medically necessary emergency care to members at sites of the HMO other than the one designated (except to the extent that the cost is insurable under Section 110.108(b)(1)).

## PHS/OHMO - § 110.102(a)(2) - basic health services: outpatient and inpatient services

> (2)(i) Outpatient services, which shall include diagnostic services, treatment services and x-ray services, for patients who are ambulatory and may be provided in a non-hospital based health care facility or at a hospital; (ii) inpatient hospital services, which shall include but not be limited to, room and board, general nursing care, meals and special diets when medically necessary, use of operating room and related facilities, use of intensive care unit and services, x-ray services, laboratory, and other diagnostic tests, drugs, medications, biologicals, anesthesia and oxygen services, special duty nursing when medically necessary, radiation therapy, inhalation therapy, and administration of whole blood and blood plasma; (iii) outpatient services and inpatient hospital services shall include short-term rehabilitation services and physical therapy, the provision of which the HMO determines can be expected to result in the significant improvement of a member's condition within a period of two months;

Q. Is it allowable for an other party to enter into contract with a hospital, on behalf of an HMO, for the provision of hospital services?

A. Yes. An other party may contract with a hospital on behalf of an HMO.

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Q. Is a contract required between an HMO or other party and a hospital for the provision of hospital services?

A. No. A contract by or on behalf of an HMO with a hospital is not required; however, an HMO must demonstrate that HMO covered services will be available and accessible to HMO members as needed.

## § 110.102(a)(3) - basic health services: medically necessary emergency services

(3) Instructions to its members on procedures to be followed to secure medically necessary emergency health services both in the service area and out of the service area;

Q. May an HMO impose a dollar limit other than allowable copayments on medically necessary emergency services provided out of the service area?

A. No. Since it is a basic health service, a medically necessary emergency service may not be limited as to time or cost (except for allowable copayments).

(4) Twenty outpatient visits per member per year, as may be necessary and appropriate for short-term evaluative or crisis intervention mental health services, or both;

Q. Is short-term outpatient therapy in support of evaluative or crisis intervention mental health services a required basic health service?

A. Yes. In addition to evaluative and crisis intervention, short-term outpatient therapy for mental conditions in support of evaluative or crisis intervention is a basic health service.

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Q. To what period of time does "20 outpatient visits per year" apply?

A. The 12 month period may be the HMO's fiscal year, a calendar year, or contract year, provided the standard applied is consistent for all members. To assure full and fair disclosure to members, the HMO must identify, in advance, the 12 month period which will apply.

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Q. When an HMO provides inpatient mental health services, is it allowable for the HMO to count the inpatient physician services for mental health against the basic health benefit for outpatient mental health services?

A. No. The 20 outpatient visits for mental health are a required basic health service. All other mental health services are considered supplemental health services, including professional services provided in the hospital. Supplemental inpatient mental health services may not be provided in lieu of the required basic outpatient health services for mental health.

(5) Diagnosis, medical treatment and referral services (including referral services to appropriate ancillary services) for the abuse of or addiction to alcohol and drugs:

(i) Diagnosis and medical treatment for the abuse of or addiction to alcohol and drugs shall include detoxification for alcoholism or drug abuse on either an outpatient or inpatient basis, whichever is medically determined to be appropriate, in addition to the other required basic health services for the treatment of other medical conditions;

(ii) Referral services may be either for medical or for nonmedical ancillary services. Medical services shall be a part of basic health services; nonmedical ancillary services (such as vocational rehabilitation and employment counseling) and prolonged rehabilitation services in a specialized inpatient or residential facility need not be a part of basic health services;

Q. Are basic health services for the abuse of or addiction to alcohol and drugs separate from the basic health service for mental health services?

A. Yes. Basic health services for the abuse of or addiction to alcohol and drugs are separate from mental health services; therefore, the provision of such services may not be counted against the requirement for at least 20 outpatient visits as may be necessary for mental health. If, however, outpatient mental health services are rendered in conjunction with services for the abuse of or addiction to alcohol and drugs, such mental health services may be chargeable to the 20 outpatient visit requirement.

## PHS/OHMO - § 110.102(a)(7) - home health services

(7) Home health services provided at a member's home by health care personnel, as prescribed or directed by the responsible physician or other authority designated by the HMO; and

Q. Are house calls within the HMO's service area a required basic health service?

A. Yes. Services provided in the home are considered home health services and are, therefore, required basic health services. A house call, which is one form of home health care, is a required basic health service. It should be noted that house calls may be provided by physicians or health professionals consistent with State laws, and need be provided only when, in the judgment of the HMO's providers, such services are medically necessary.

--------

Q. What are some permissible ways for an HMO to provide home health services?

A. An HMO may provide home health services either through health care personnel employed by the HMO or through a contract with a home health agency. For purposes of the certification requirement of Section 110.108(k), the Department considers home health agencies to be "institutional providers." Therefore, if an HMO elects to contract with a home health agency, that agency must be certified as provided in Section 110.108(k) (i.e., in accordance with the regulations governing participation of providers in the Medicare or Medicaid program; or where home health services are provided by a hospital, pursuant to the standards and procedures of the Joint Commission on Accreditation of Hospitals).

(8) Preventive health services, which shall be made available to members and shall include at least the following:

(i) A broad range of voluntary family planning services;

(ii) Services for infertility;

(iii) Well-child care from birth;

(iv) Periodic health evaluation for adults;

(v) Eye and ear examinations for children through age 17, to determine the need for vision and hearing correction; and

(vi) Pediatric and adult immunizations, in accord with accepted medical practice.

Q. Do pediatric and adult immunizations include biologicals and their administration?

A. Yes. Biologicals and their administration are integral components of medically necessary immunizations.

## PHS/OHMO - § 110.102(b) - supplemental health service included in the basic health services package

(b) In addition, an HMO may include a health service described in § 110.103 as a supplemental health service in the basic health services which it provides or arranges for its members for a basic health services payment.

Q. Is it allowable for the HMO to place limits of time or cost on supplemental benefits which are included in the basic benefits package?

A. Yes. Neither the Act nor the regulations place restrictions on supplemental services with respect to time or cost. In addition, the requirement that copayments be nominal does not apply to supplemental health services. However, all supplemental services offered on a prepaid basis must be community rated (See Section 110.106(b) for two exceptions to this rule).

## PHS/OHMO - § 110.102(c) - HMO good-faith effort to provide services

> (c) To the extent that a natural disaster, war, riot, civil insurrection, epidemic or any other emergency or similar event not within the control of an HMO results in the facilities, personnels, or financial resources of an HMO being unavailable to provide or arrange for the provision of a basic or supplemental health service in accordance with the requirements of this subpart, the HMO is required only to make a good-faith effort to provide or arrange for the provision of the service, taking into account the impact of the event. For purposes of this paragraph, an event is not within the control of an HMO if the HMO cannot exercise influence or dominion over its occurrence.

Q. Are strikes or labor disorders within an HMO considered events outside the HMO's control with regard to its ability to provide health services to the membership?

A. No. An event not within the control of an HMO is defined as one where the HMO cannot exercise influence or dominion over its occurrence. Accordingly, labor disputes within the HMO are not considered events outside the control of the HMO.

## PHS/OHMO - § 110.102(d) - exclusions from basic health services

(d) The following are not required to be provided as basic health services:

(1) Corrective appliances and artificial aids;

(2) Mental health services, except as required under section 1302(1)(D) of the Act and paragraph (a)(4) of this section;

(3) Cosmetic surgery, unless medically necessary;

(4) Prescribed drugs and medicines incidental to outpatient care;

(5) Ambulance services, unless medically necessary;

(6) Care for military service connected disabilities for which the member is legally entitled to services and for which facilities are reasonably available to this member;

(7) Care for conditions that State or local law requires be treated in a public facility;

(8) Dental services;

(9) Vision and hearing care except as required by sections 1302(1)(A) and 1302(1)(H)(vi) of the Act and paragraphs (a)(1) and (a)(8) of this section;

(10) Custodial or domiciliary care;

(11) Experimental medical, surgical, or other experimental health care procedures, unless approved as a basic health service by the policymaking body of the HMO;

(12) Personal or comfort items and private rooms, unless medically necessary during inpatient hospitalization;

(13) Whole blood and blood plasma;

(14) Long-term physical therapy and rehabilitation;

(15) Durable medical equipment for home use (such as wheel chairs, surgical beds, respirators, dialysis machines); and

**(16) Health services which are unusual and infrequently provided and not necessary for the protection of individual health, as approved by the Secretary upon application by the HMO.**

Q. Is it allowable for an HMO to exclude health benefits which are not specifically authorized as exclusions in the regulations?

A. No. The only permissible exclusions are listed in Section 110.102(d). However, an HMO may seek the Secretary's approval for additional exclusions under Section 110.102(d)(16), as discussed below.

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Q. When must application be made to the Secretary for a determination that a service may be excluded because it is unusual and infrequently provided and not necessary for the protection of individual health?

A. An application to exclude services considered "unusual and infrequently provided" may be made either in anticipation of service demands or after a particular service has been requested by a member. The application should cite the HMO's justification for requesting the exclusion, including appropriate medical evidence to support its view. The application for exclusion is to be submitted to the Director, Office of Health Maintenance Organizations. Notices of exclusions approved will be published in the Federal Register and the Secretary will indicate in the notice whether all HMOs may exclude the service without further application. Consistent with requirements for full and fair disclosure, such information must be made known to members and prospective members by the HMO.

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continued on next page ...

## PHS/OHMO - § 110.102(d) - exclusions from basic health services (con't)

(d) The following are not required to be provided as basic health services:

(1) Corrective appliances and artificial aids;

(2) Mental health services, except as required under section 1302(1)(D) of the Act and paragraph (a)(4) of this section;

(3) Cosmetic surgery, unless medically necessary;

(4) Prescribed drugs and medicines incidental to outpatient care;

(5) Ambulance services, unless medically necessary;

(6) Care for military service connected disabilities for which the member is legally entitled to services and for which facilities are reasonably available to this member;

(7) Care for conditions that State or local law requires be treated in a public facility;

(8) Dental services;

(9) Vision and hearing care except as required by sections 1302(1)(A) and 1302(1)(H)(vi) of the Act and paragraphs (a)(1) and (a)(8) of this section;

(10) Custodial or domiciliary care;

(11) Experimental medical, surgical, or other experimental health care procedures, unless approved as a basic health service by the policymaking body of the HMO;

(12) Personal or comfort items and private rooms, unless medically necessary during inpatient hospitalization;

(13) Whole blood and blood plasma;

(14) Long-term physical therapy and rehabilitation;

(15) Durable medical equipment for home use (such as wheel chairs, surgical beds, respirators, dialysis machines); and

(16) Health services which are unusual and infrequently provided and not necessary for the protection of individual health, as approved by the Secretary upon application by the HMO.

Q. What are examples of services which would be considered by the Secretary as unusual and infrequently provided and not necessary for the protection of individual health?

A. Transsexual surgery and reversal of voluntary sterilization are services which the Secretary has approved as exclusions. The Secretary has indicated the general applicability of the exclusions for these services.

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Q. Are blood derivatives allowable exclusions from basic health services?

A. Yes. However, the administration of blood derivatives is a basic service under Section 110.102(a)(2)(ii).

## PHS/OHMO - § 110.103(a) - supplemental health services

**§ 110.103 Health benefits plan: supplemental health services.**

(a) Each HMO may provide to its members any of the following health services, which may be limited as to time and cost:

(1) Services of facilities for intermediate and long-term care;

(2) Vision and hearing care not included as a basic health service;

(3) Dental services;

(4) Mental Health services not included as a basic health service;

(5) Long-term physical medicine and rehabilitative services (including physical therapy);

(6) Prescription drugs prescribed in the course of the provision by the HMO of basic outpatient or supplemental health services; and

(7) Other health services which are not included as basic health services.

Q. Must an HMO obtain the approval of the Secretary before it offers "other health services which are not included as basic health services?"

A. No. Specific approval is not required for including a service which is not a basic health service among the supplemental health services which an HMO may offer. However, the discretion to add supplemental health services to the basic health service package does not extend to eliminating a basic health service in exchange for adding a supplemental service. An HMO must provide at least basic health services to all its members unless otherwise permitted under the Act.

## PHS/OHMO - § 110.104(a)(1) - arrangements for HMO providers

**§ 110.104 Providers of basic and supplemental health services.**

(a)(1) The HMO shall provide that the services of health professionals which are provided as basic health services will, except as provided in paragraph (e) of this section, be provided or arranged for through (i) health professionals who are staff of the HMO, (ii) a medical group or groups, (iii) an IPA or IPAs, (iv) physicians or other health professionals under direct service contracts with the HMO for the provision of these services, or (v) any combination of staff, medical group or groups, IPA or IPAs, or physicians or other health professionals under direct service contracts with the HMO.

Q. Must an HMO be designated as one of the "models" described, that is, as a staff, medical group, or IPA, or can an HMO be designated as more than one model category?

A. For purposes of Section 1310, an HMO must be designated as either a staff, medical group, or IPA model. Where there is a combination of staff and medical group, the HMO is designated as a medical group; where there is an IPA and a medical group, the HMO is designated as an IPA.

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Q. For an IPA model HMO to obtain Federal qualification, when must the IPA entity be established?

A. When Title XIII grant or loan guarantee assistance is involved, the IPA entity must be established prior to the award of funds for initial development. An entity seeking qualification as an IPA model HMO which did not receive such assistance must have an IPA entity in operation when the HMO becomes operational. In order for the Secretary to be assured that the IPA will be operating as required, the HMO must be able to document, at the time of the qualification site visit, that the IPA with which it is to be affiliated has made sufficient progress toward becoming operational.

## PHS/OHMO - § 110.104(a)(2) - physician sharing

> **(2) A staff or medical group model HMO may have as providers of basic health services physicians who have also entered into written services arrangements with an IPA or IPAs, but only if either (i) these physicians number less than 50 percent of the physicians who have entered into arrangements with the IPA or IPAs, or (ii) if the sharing is 50 percent or greater, the Secretary approves the sharing as being consistent with the purposes of section 1310(b) of the Act.**

Q. What factors will the Department consider in examining physician sharing of 50 percent or more between an IPA and medical group or staff HMO?

A. The Secretary will, on a case-by-case basis, review the characteristics of those HMOs which share physicians in excess of the 50 percent limitation, taking into account the following factors:

1. The total number of practicing physicians in the service area of each HMO which proposes to share physicians with another HMO;
2. The number of physicians to be shared as a percentage of the IPA's total pool;
3. The specialties of the shared physicians;
4. The overlap of the service areas of the HMOs which propose sharing;
5. The practice location of the shared physicians in relation to the location of the other HMO physician providers; and
6. Such other factors as the Secretary may consider necessary in determining whether the sharing of physicians enables the HMOs to meet the purpose of Section 1310(b).

## PHS/OHMO - § 110.104(a)(3) - waiver of the medical group coordinated practice of medicine requirement

(3) Within the 4 year period beginning with the month following the month in which an HMO becomes a qualified HMO, physician services which are basic health services may also be provided by a non-conforming medical group. After this 4 year period, the HMO may use this entity to provide physician services which are basic health services only if (i) the entity meets the definition of medical group in § 110.101, or (ii) the Secretary determines that the principal professional activity (over 50 percent individually) of the entity's members is the coordinated practice of their profession, and if the HMO has demonstrated to the satisfaction of the Secretary that the entity is committed to the delivery of medical services on a prepaid group practice basis by either:

(A) Presenting a reasonable time-phased plan for the entity to achieve compliance with the "substantial responsibility" requirement of Subparagraph (3)(i) of the definition of "medical group" in § 110.101. The HMO shall update the plan annually and shall demonstrate to the satisfaction of the Secretary that the entity is making continuous efforts and progress towards compliance with the requirements of the definition of "medical group," or,

(B) Demonstrating that compliance by the entity with the "substantial responsibility" requirement is unreasonable or impractical because *(1)* the HMO serves a non-metropolitan or rural area as defined in § 110.101, or *(2)* the entity is a multi-specialty group which provides medical consultation upon referral on a regional or national basis, or *(3)* the majority of the residents of the HMO's service area are not eligible for employer-employee health benefits plans and the HMO has an insufficient number of members to require utilization of at least 35 percent of the entity's services.

Q. Can an HMO receive a waiver of the requirement that 50 percent of the professional activity of each medical group member be the coordinated practice of medicine?

A. No. As of four years after qualification, the HMO can obtain a waiver only of the "substantial responsibility" requirement. However, it need not have a medical group which complies with the "principal professional activity" requirement for the four year period following qualification.

## PHS/OHMO - § 110.105(a)(1) - periodic payment for basic health services

> **§ 110.105 Payment for basic health services.**
>
> (a) *Basic health services payment.* Each HMO shall provide or arrange for the provision of basic health services for a basic health services payment which:
>
> (1) Is to be paid on a periodic basis without regard to the dates these services are provided;

Q. Are there Federal statutory or regulatory restrictions regarding the frequency of HMO rate changes?

A. No. The HMO determines the frequency of rate changes subject to state law and to any agreed upon arrangements with employing entities or subscribers.

## PHS/OHMO - § 110.105(a)(4) - copayment requirements

**(4) May be supplemented by nominal copayments which may be required for the provision of specific basic health services. Each HMO may establish one or more copayment options calculated on the basis of a community rating system.**

Q. Must a copayment imposed on medically necessary health services obtained other than through the HMO be the same as the copayment the HMO would have charged for the same service obtained through the HMO?

A. No. An HMO is permitted to impose different copayment charges so long as these charges do not exceed the limitations of Section 110.105(a)(4).

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Q. In addition to or in lieu of copayments, may the HMO impose deductibles?

A. No. Premiums may be supplemented only by nominal copayments in accordance with Section 110.105(a)(4).

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Q. What is the effect of the amendments to Title VII of the Civil Rights Act known as the Pregnancy Discrimination Act (P.L. 95-555) on HMO copayments for maternity services and on an HMO's inclusion in an employer's health benefits plan under Section 1310 of the Public Health Service Act (dual choice)?

A. The Pregnancy Discrimination Act applies only to employers, not to HMOs except insofar as they are employers. To be in compliance with the provisions of the Pregnancy Discrimination Act, an employer may not offer a plan which contains copayments applicable to maternity but not to other inpatient services. Further, any copayment amounts for inpatient hospital services must be the same regardless of whether the admission is for maternity or non-maternity services. If an HMO does not comply with an employer's request to bring its maternity practices into compliance with the Pregnancy Discrimination Act, the Secretary will not initiate proceedings to assess a civil penalty against the employer if the employer refuses to include the HMO in its health benefits plan.

## PHS/OHMO - § 110.105(a)(4)(i) - copayment requirements

**(i) An HMO may not impose copayment charges that exceed 50 percent of the total cost of providing any single service to its members, nor in the aggregate more than 20 percent of the total cost of providing all basic health services.**

Q. Is an HMO required to notify all members and prospective members of copayment amounts for every type of service?

A. Yes. An HMO shall, in advance, advise members and prospective members of its copayment policy in all cases, consistent with the requirements under Section 110.108(c) for full and fair disclosure. Specifically, the HMO must identify clearly which services are subject to copayment and the established copayment for that service.

## PHS/OHMO - § 110.105(a)(4)(ii) - copayments for basic health services

(ii) To insure that copayments are not a barrier to the utilization of health services or membership in the HMO, an HMO may not impose copayment charges on any subscriber (or members covered by the subscriber's contract with the HMO) in any calendar year, when the copayments made by the subscriber (or members) in that calendar year total 100 percent of the total annual premium cost which that subscriber (or members) would be required to pay if he (or they) were enrolled under an option with no copayments. This limitation applies only if the subscriber (or members) demonstrates that copayments in that amount have been paid in that year.

Q. Is the HMO responsible for disclosing to its members the copayment amount that the member must pay before the limit on copayments becomes effective?

A. Yes. The HMO is responsible under the requirements of Section 110.108(c) for full and fair disclosure to members to provide specific information on the copayment dollar limitation.

## PHS/OHMO - § 110.105(b)(1) and (2) - community rating system

(b) *Community rating system.* Under a community rating system, rates of payment for health services may be determined on a per-person or per-family basis and may vary with the number of persons in a family. Except as otherwise authorized in this paragraph, these rates must be equivalent for all individuals and for all families of similar composition. Rates of payment may be based on either a schedule of rates charged to each subscriber group or on a per-member-per-month (or per-subscriber-per-month) revenue requirement for the HMO. In the former event, rates may vary from group to group if the projected total revenue from each group in substantially equivalent to the revenue which would be derived if the schedule of rates were uniform for all groups. In the latter event, the payments from each group of subscribers shall be calculated to yield revenues substantially equivalent to the product of the total number of members (or subscribers) expected to be enrolled from the group and the per-member-per-month (or per-subscriber-per-month) revenue requirement for the HMO. In addition, a community rating system must meet the following requirements:

(1) Rates of payment may not vary because of actual or anticipated utilization of services by individuals associated with any specific group of subscribers. These provisions do not preclude changes in the rates of payment which are established for new enrollments or reenrollments and which do not apply to existing contracts until the renewal of these contracts.

(2) Rates of payment shall reflect differences in benefits and copayment requirements.

Q. What are the allowable methods for establishing prepaid rates for basic and supplemental services under a community rating system?

A. See attached community rating paper prepared by the Office of Health Maintenance Organizations for distribution on May 29, 1979.

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Q. Are HMOs allowed to apply the different community rating methods, described in Part IV of the community rating paper, to different groups at the same time?

A. No. An HMO must select one of the methods and use that method consistently for all groups of enrollees for which the community rating requirement applies. The HMO may change methods, but it must apply the new method consistently.

May 29, 1979

# ESTABLISHING PREPAID RATES FOR FEDERALLY QUALIFIED HEALTH MAINTENANCE ORGANIZATIONS UNDER A COMMUNITY RATING SYSTEM

## Introduction

The purpose of this paper is to set forth the basis for determining whether an HMO establishes its prepaid rates for basic and supplemental health services under a community rating system as required by the Health Maintenance Organization Act.

The general outline of the paper is as follows. Section I describes community rating as it has been defined historically, distinguishes community rating from experience rating, and gives reasons why HMOs and their prototypes have preferred to use community rating. Section II describes the community rating requirements of the HMO Act and includes a discussion of the legislative intent in amending the Act to take into account a variety of group rating practices used by HMOs. Section III provides a list of general principles for determining whether an HMO's prepaid rates are in conformity with the Act's requirements. Finally, Section IV describes and illustrates rate making practices which are permissible under a community rating system.

## I. The community rating concept

### A. Community rating contrasted with experience rating

Both community rating and experience rating are applications of the insurance principle of spreading risk to minimize the likelihood of individual financial catastrophe. However, unlike experience rating, community rating encourages the widest participation of various population segments by averaging the cost of the total population to reduce high rates for high risk groups.

A fundamental distinction between community rating and experience rating relates to the nature and size of the population that is used as the base for rate-setting. In a community rated plan, the "community" is generally understood to mean the plan's entire membership. Alternatively, under experience rating, each large group is a separate population base and very small groups are pooled to make one or more large groups.

One author has distinguished between community rating and experience rating as follows:

> "When an insuring agency charges the same premium for the same benefits to all individuals or groups regardless of age and sex composition and cost experience of the insured, it is said to employ a

> community rate. If the agency uses an experience rate, it varies premiums according to the cost experience of each group covered; members of some groups then pay higher average premiums than members of other groups. Under this arrangement, therefore, the cost of health insurance is not spread equally among groups."1/

Community rating was widely used by Blue Cross Plans, beginning in the 1930's, based on the perception that resulting premiums would be most attractive to a broad cross section of the population and that enrollment would thus be maximized. However, stiff competition from commercial insurance plans forced Blue Cross to reconsider and in the 1950's, it began to abandon community rating.2/ Today, Blue Cross, Blue Shield, and commercial insurers all experience rate.

B. Reasons for Community Rating

Historically, there have been compelling reasons for group practice prepayment plans and for other HMO prototypes to community rate.

1. First, maximum stability and predictability of rate revenues can be achieved under community rating. Wide year-to-year fluctuations in the utilization and cost of services by individuals or groups do not result in wide fluctuations in their rates under community rating. However, such fluctuations do occur under experience rating, in part because of shifting utilization and costs and in part because of the practice of rebating premium revenue to groups which have better than projected experience for a particular period.3/

Revenue stability and predictability make planning easier, both from the standpoint of the HMO and of the individual or

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1/ Odin W. Anderson, The Uneasy Equilibrium, College and University Press, New Haven, Conn., 1968, Page 202.

2/ Commercial insurers were able to offer healthy groups lower rates under experience rating than Blue Cross could under community rating. To the extent that commercial insurers were successful in attracting healthy groups from Blue Cross, the residual population of higher risk Blue Cross enrollees had ever increasing community rates leading to competitive disadvantages.

3/ The practice of rebating premium revenue creates inflationary pressures. In order to provide for rebate requirements, experience rated plans must establish sufficient reserves. Premium rates must be higher to maintain such reserves and in this respect experience rating is inflationary.

group. Of most importance, the stability achieved under community rating is crucial for essentially fixed cost plans which must maintain professional staffs, equipment, and facilities to meet their responsibilities to provide or arrange services for enrolled members.

2. Second, community rating is less costly to administer than is experience rating. It is not necessary under this rate making method to keep track of the costs and utilization of specific services provided to specific individuals or to groups. Of course, the maintenance of records of such costs and utilization is required under experience rating.

3. Third, community rating is simple and easy to understand. Also, the basis for prepaid rates can be easily explained and justified to individuals or to representatives of enrolled groups.

4. Fourth, community rating makes plans more accessible for high risk individuals and groups. It permits plans to serve a broad cross section of the general community. This was one of the key reasons for requiring community rating under the HMO Act. The following is an excerpt from the report on the HMO Act by the House Committee on Interstate and Foreign Commerce.

> "The use of experience rating has in practice tended to make health services most expensive for groups which are at highest risk, and thus usually least able to afford services. It has also encouraged HMOs to seek out groups of enrollees who will be the least expensive for that HMO to take care of. The Committee has chosen to require community rating so that prices for services will be uniform for all of the members enrolled in an HMO and, thus, so that individuals who have the highest risk will not also be required to pay the highest prices. This will limit somewhat, the HMO's incentive to seek out and care for only the healthiest members of the population."[4]

The Senate Committee on Labor and Public Welfare gave a similar reason as follows:

> "Another closely related and equally widespread practice, known as experience rating, enables

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[4] House of Representatives, Report by the Committee on Interstate and Foreign Commerce on the Health Maintenance Organization Act of 1973, Report No. 93-451, pp. 23 and 24.

> health insurers to charge premium rates based upon the actual claims experience of a particular group of subscribers. This has the practical impact of lowering the cost of health insurance for 'low risk' or relatively healthy population groups, while at the same time raising costs and diminishing the availability of health insurance for those suffering from costly illnesses. The aged and chronically ill, who are least able to afford health insurance, end up paying the highest costs for premiums. Mindful of these facts, the Committee has included provisions requiring that Federally funded HMOs and HSOs charge a uniform rate (with the exception of family rates) to all its enrollees."5/

## II. HMO Act community rating requirements

Subsection 1301(b)(1) of the Health Maintenance Organization Act requires qualified HMOs to provide basic health services for a basic health services payment which is fixed under a community rating system. Subsection 1301(b)(2) requires qualified HMOs which provide supplemental health services on a prepayment basis to fix payment for such services under a community rating system.6/

Subsection 1301(8) in part provides:

> "The term 'community rating system' means a system of payments for health services. Under such a system rates of payments may be determined on a per person or per family basis and may vary with the number of persons in a family, but except as otherwise authorized in the next sentence, such rates must be equivalent for all individuals and for all families of similar composition."

This subsection then goes on to describe the authorized exceptions.7/

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5/ U.S. Senate, Report of the Committee on Labor and Public Welfare on the Health Maintenance Organization and Resources Act of 1973, Report No. 93-129, pp. 29 and 30.

6/ The HMO amendments of 1976 allow entities which provide comprehensive health services on a prepaid basis to become qualified without fixing rates under a community rating system for 48 months following their qualification.

7/ The subsection provides that there may be nominal differentials in rates to reflect differences in administrative costs of collecting payments, differences in marketing costs, and compositing. Moreover, the subsection exempts from community rating persons who are entitled to health benefits under certain government programs (*e.g.*, Medicare and Medicaid).

Subsequent to the passage of the Act and based on a review of the community rating system of prototype HMOs, it became apparent that the Act did not define community rating in a manner that was consistent with some group purchasers' existing practices in making payments to HMOs, even though such practices did not involve experience rating. This problem was brought to the attention of Congress which then amended the Act as follows:

> "Nominal differentials in such rates may be established to reflect the compositing of the rates of payment in a systematic manner to accommodate group purchasing practices of the various employers."

The Senate Committee on Labor and Public Welfare explained the reason for this amendment:

> "Section 6(c) amends the Community Rating requirement in P.L. 93-222 to recognize existing practices for the determination of rates by employers and other purchasers of health care. Further, many HMOs and existing prototypes of HMOs have variations in their determination of rates which are precluded by the existing language. Because of these practices, employers and HMOs would have difficulty in complying with the rigidly stated community rating provisions of the present Act.
>
> Many employers for example follow a composite rating system whereby individual rates are increased somewhat so that family rates can be lowered. In the case of HMOs and HMO type plans some have a two step rate, individual and family, a three step rate, individual, coupled, and family, while still others may have a rate for a family which varies according to the number of individuals in a family. In all such cases, the rates are based upon a basic per individual rate.
>
> It is not the intent of the Committee to change the obligation of the HMO to operate under a community rating system. The language amendment simply authorized the Secretary to take into account the varying ways in which the community rating is determined under existing practices."[8]

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[8] U.S. Senate, Report from the Committee on Labor and Public Welfare on S. 1926, Health Mantenance Organization Amendments of 1976, Report No. 94-844, p. 16.

Although the amendment authorized the continuation of existing practices there was still an absence of a basis for determining which deviations from the strict requirements of the original Act were covered by the amended Act. The following principles were developed to achieve this objective.

## III. General community rating principles

This section sets forth principles which provide the basis for determining whether an HMO's prepaid rates are established under a community rating system.

Principle 1 Rates for an individual, family, or group cannot be based on the specific utilization or cost experience of that individual, family, or group. (This principle specifically forbids experience rating.)

Principle 2 For non-group enrollees, prepaid rates must be equivalent for all individuals and for all families of similar composition if their benefits are equivalent (unless otherwise excepted by the Act and Regulations). For group enrollees, prepaid rates for all individuals and for all families of similar composition must be equivalent to those of non-group enrollees if benefits are equivalent unless the conditions set forth in other principles are met or unless otherwise excepted by the Act and Regulations. (Under this principle, the rates of non-group members become the benchmark. If the rates of group members are the same as those of non-group members the community rating test is met.)

Principle 3 Each plan must have a defined community rate standard, applicable to all plan enrollees, that provides the basis for deriving prepaid rates. The standard may be a rate structure, an average per member per month revenue requirement, or an average per subscriber per month revenue requirement. It is permissible under a community rating system for an HMO to establish prepaid rates which vary from group to group provided that each group's rates are derived from the standard and that the total projected rate revenue from each group is substantially equivalent to what would be generated under the application of the standard.

(Illustrative examples of how this principle is applied are given in Section IV.)

Principle 4 Variations in rates are permissible if they reflect differences in benefits (including differences in copayment levels), differences in administrative and marketing costs within defined group categories, and differences in groups' contract effective dates.

Although the Act requires that rates must be equivalent for all individuals and families of similar composition, it does not address how differences in benefits, copayment levels and contract effective dates should be taken into account. Many HMOs offer a variety of plans with different benefits and various copayment levels. In addition an HMO may enter into annual contracts with groups at different times during the HMO's fiscal year. When this happens, groups with earlier contract renewal dates pay rate increases before groups with later contract renewal dates resulting in rate differentials.

In determining whether a community rating system meets the requirements of the Act, differences must be allowed for groups with different benefits, copayments and contract effective dates. Otherwise, members with fewer benefits would subsidize those with more benefits, those with larger copayments would subsidize those with smaller or no copayments, and all rates changes would have to occur at the same time regardless of the effective dates of contract renewals.

If it can be shown that prepaid rates for a group are established in a manner consistent with the above principles, the rates are in conformity with the community rating requirements of the Act and Regulations.

The following section gives illustrative examples of how these principles are applied. Part A describes alternative methods that may be used to establish a community rate standard. Part B illustrates a variety of group rating practices which meet the test of what is permissible under a community rating system.

## IV. Applications of the community rating principles

### A. Alternative methods for establishing a community rate standard

Principle 3 requires that each HMO should have a defined standard, applicable to all plan enrollees, that provides the basis for deriving each group's rates. Illustrations of alternative methods for deriving such a standard are given below.

### 1. The HMO employs a standard rate structure

Under this approach, an HMO may establish a standard rate structure (*e.g.*, a three-tiered structure[9] having a fixed relationship between rate-steps[10] for each of its coverages. Under the standard structure, the premium rate should be the same for all families of the same sizing having the same benefits and the same contract effective date, irrespective of group affiliation (unless otherwise excepted by the Act).

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[9] A structure under which a subscriber pays one rate, a subscriber with one dependent pays another rate, and all subscribers with two or more dependents pay a third rate.

[10] "Step" refers to an individual rate in the rate structure. (For example, the rate for a subscriber only is referred to as the first-step rate, the rate for a subscriber and one dependent is referred to as the second-step rate, etc.)

The following is an example of how an HMO might translate its projected annual revenue requirement into a standard rate structure.

| | |
|---|---|
| Average number of members for year | 30,000 |
| Total projected member months for year | 360,000 |
| Total revenue needed | $10,800,000 |

If it is assumed for purpose of simplication that all 30,000 members have the same contract period (effective January 1st), and that there is no copayment revenue, then it follows that the average rate revenue requirement is $30 per member per month (i.e., $10,800,000 ÷ 360,000 member months).

The HMO may desire that its standard rate structure be a three-tiered structure having a fixed ratio relationship (i.e., 1:2:3) between rate steps.[11] Assuming for the entire HMO community that 30% of all subscribers are single subscribers, 20% are 2 party families (i.e., subscribers with one dependent), 50% are 3+ party families (i.e. subscribers with two or more dependents), and there are on the average 2.45 members per contract (i.e., per subscriber), the $30 requirement would translate into standard rates of:

| | |
|---|---|
| Single subscriber | $ 33.41[12] |
| 2 party subscriber | 66.82[12] |
| 3+ party subscriber | 100.23[12] |

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[11] The HMO standard rate structure may be other than a three-tiered structure. Moreover, the ratio relationship between steps may be whatever the HMO deems to be appropriate.

[12] In this illustrative example, the premium rates are derived as follows:

(a) A first-step conversion factor is computed according to the following formula:

$$\frac{2.45 \text{ (members per subscriber)}}{(.30 \times 1) + (.20 \times 2) + (.50 \times 3)\ *} = \frac{2.45}{2.20} = 1.1136$$

* The denominator represents the family composition weighted by the desired step relationships.

(b) The first-step conversion factor (1.1136) times the $30 requirement equals the single subscriber rate ($33.41).

(c) The 2 party and 3+ party rates are, respectively, twice and three times the single subscriber rate.

A reconciliation of these standard rates and the $30 requirement is provided below for the entire HMO community:

| (1) Type of Contract | (2) % Dist'n of Contracts | (3) Average Contract Size | (4) Wtd. Avg. Contract Size (Col. 2 x Col. 5) | (5) Prepaid Rate | (6) Weighted Average Rate (Col. 2 x Col. 3) |
|---|---|---|---|---|---|
| Single | 30% | 1 | .30 | $ 33.41 | $10.023 |
| 2 party | 20 | 2 | .40 | 66.82 | 13.364 |
| 3+ party | 50 | 3.5 | 1.75 | 100.23 | 40.115 |
| | 100% | | 2.45 | | $73.502 |

The average rate per subscriber ($73.502) divided by the average number of members per subscriber (2.45) yields the $30 requirement. Thus, if all single subscribers were charged $33.41, if all 2 party subscribers were charged $66.82, and if all 3+ party subscribers were charged $100.23, the HMO's revenue requirement would be met.

The HMO's standard rate structure would be composed of these 3-tiered rates. However, as will be illustrated below, it is permissible under a community rating system for groups (or clusters of groups) to have rates which vary from the standard structure. The test of whether such varying rates are permissible is that the projected total revenue derived from the group (or clusters of groups) should be substantially equivalent to what would be paid were rates based on the standard rate structure.

### 2. The HMO uses a standard per member per month amount as the basis for determining each group's rates

Under this alternative, an HMO may establish prepaid rates which vary from group to group (or among clusters of groups), provided that the average per member per month revenue yield from all groups having the same benefits and the same contract effective dates is substantially equivalent to a community per member per month standard (unless otherwise excepted by the Act). The rates would be the same for all families of the same size in each group (or cluster of groups) but would be different for families of the same size in different groups.

To illustrate, assume that the HMO's standard rate revenue requirement is $30 per member per month. Assume, moreover, that the HMO has two groups with the following three-tiered rates:

| | Group A | Group B |
|---|---|---|
| Single | $32.50 | $ 40.00 |
| 2 party | 61.70 | 80.00 |
| 3+ party | 93.47 | 100.00 |

As shown below, both groups would generate the same per member per month standard revenue:

| | Type of Contract | % Dist'n.of Contracts | Average Contract Size | Wtd.Avg. Contract Size | Prepaid Rate | Weighted Average Rate |
|---|---|---|---|---|---|---|
| Group A | Single | 25% | 1 | .25 | $32.50 | $ 8.125 |
| | 2 party | 30 | 2 | .60 | 61.70 | 18.510 |
| | 3+ party | 45 | 3.2 | 1.44 | 93.47 | 42.065 |
| | | 100% | | 2.29 | | $68.700 |
| Group B | Single | 35% | 1 | .35 | $ 40.00 | $14.00 |
| | 2 party | 20 | 2 | .40 | 80.00 | 16.00 |
| | 3+ party | 45 | 3.89 | 1.75 | 100.00 | 45.00 |
| | | 100% | | 2.50 | | $75.00 |

Dividing the weighted average rate for each group by the average number of members per subscriber in that group yields the standard requirement of $30 per member per month.

Group A $68.70 per subscriber ÷ 2.29 members per subscriber = $30.00

Group B $75.00 per subscriber ÷ 2.50 members per subscriber = $30.00

### 3. The HMO uses a standard per subscriber per month amount as the basis for determining each group's rates

The use of this approach would require that the rates for each group (or cluster of groups) yield an amount substantially equivalent to an average per subscriber per month standard (unless otherwise excepted by the Act). The rates would be the same for all families of the same size in each group (or cluster of groups) but would be different for families of the same size in different groups.

Groups A and B, with the characteristics given in Section A-2, would each yield $72.60 per subscriber per month, based on the following three-tiered rates:

| | Group A | Group B |
|---|---|---|
| Single | $33.00 | $38.72 |
| 2 party | 66.00 | 77.44 |
| 3+ party | 99.00 | 96.80 |

## B. Illustrative examples of group rating practices which are permissible under community rating

In this section, illustrative examples are given of permissible methods for establishing prepaid rates for individual groups. To ascertain whether a group's prepaid rates meet community rating requirements, it must be shown that the method for establishing rates is consistent with the principles described in Section III, unless otherwise excepted by the Act and Regulations.

### 1. Compositing

Compositing involves the restructuring of the HMO's rates in order to meet the needs of individual group purchasers or to conform to the existing rate structures of competing health benefit plans. A commonly used approach is to collapse a 3-tiered structure to a 2-tiered structure or to a single composite. Whether a group pays on a 3-tiered, 2-tiered, single composite, or some other rate structure basis, the total revenue derived from the group should be substantially equivalent.

The following examples show how compositing is accomplished.

Example a Establishing a single composite:

Assume the HMO has a standard three-tiered rate structure with the following rates: (Refer to the data given in Section A-1, which illustrates the computation of three-tiered rates under a standard rate structure).

| | |
|---|---|
| Single subscriber | $ 33.41 |
| 2 party subscriber | 66.82 |
| 3+ party subscriber | 100.23 |

The following table shows how much total revenue would be derived from a hypothetical group C, given the application of the standard structure:

| Type of Contract | Number of Subscriber Units | Prepaid Rate | Total Revenue |
|---|---|---|---|
| Single | 38 | $ 33.4 | $1,269.58 |
| 2 party | 18 | 66.82 | 1,202.76 |
| 3+ party | 44 | 100.23 | 4,410.12 |
| | 100 | | $6,882.46 |

Suppose, in order to conform with the needs of group C, that the HMO must charge a single composite. This would be achieved by dividing the total revenue required from the group by its total number of subscribers. For group C, the single composite would be $68.82.

If, alternatively, the HMO fixes its rates for each group on the basis of a defined per member per month standard (*e.g.*, \$30), a single composite would be achieved by multiplying the standard by each group's average contract size. Thus, if the average number of members per contract in group B is projected to be 2.50, the single composite would be \$75.00.

For plans which use a per subscriber per month amount as the community rate standard, the single composite for each group would be the per subscriber per month standard.

Example b Establishing a two-tiered rate:

Assume group C (refer to the above example) desires to maintain the standard single subscriber rate and have a second rate applicable to all families (one form of two-step compositing). There is only one second-step rate that will satisfy the total revenue requirement of \$6,882.46. This rate is computed by subtracting the revenue required on behalf of single subscribers from the total revenue requirement and dividing the difference by the number of two-or-more person subscriber units in the group, *i.e.*, (\$6,882.46 - \$1,269.58) ÷ (18 + 44) = \$90.53.

As shown below, the resulting two-tiered rate structure yields the same revenue for group C as does the standard structure:

| Type of Contract | Number of Subscriber Units | Prepaid Rate | Total Revenue |
|---|---|---|---|
| Single | 38 | \$33.41 | \$1,269.58 |
| 2+ party | 62 | 90.53 | 5,612.86 |
|  | 100 |  | \$6,882.44 |

### 2. Altering rate step relationships

Under community rating, it is permissible to vary the ratio relationships (*i.e.*, the loading factors) between rate steps in a group's rate structure provided that the total revenue generated from the group using the altered relationship is substantially equivalent to what would be obtained from the group if it were charged on the basis of the community rate standards.

Example a Rate-setting which takes into account employer contributions:

Some employers only contribute to the cost of covering an employee and the additional costs of covering dependents, if any, must be borne entirely by the employee. Not uncommonly, the employer's contribution is based on the single subscriber rate of a competing indemnity carrier and is higher than the standard single rate charged by the HMO for the group's benefit package. The HMO may alter its rate structure for a given group to take maximum advantage of the employer's contribution.

For example, assume that the standard three-tiered rates and data given for group C in the compositing example apply. Suppose that the employer's contribution is 100% of the single subscriber rate for the alternate carrier (*i.e.*, $40) and that the HMO desires that its single subscriber rate for group C be fixed at this amount under a three-tiered rate structure. The following is a derivation of the HMO's rates:

| Type of Contact | Number of Subscriber Units | Average Contract Size | Prepaid Rate | Total Revenue Requirement |
|---|---|---|---|---|
| Single | 38 | 1 | $40 | $1,520 |
| 2 party | 18 | 2 | x | 5,362 |
| | 44 | 2.5 | 1.5[13] | |
| | 100 | | | $6,882 |

The 2 party rate, x, may be solved, according to the following equation:

[38 ($40) + 18 (x) + (1.5x)] = $6,882;

x = $63.83 (the 2 party rate)

1.5x = $95.75 (the 3+ party rate)

The altered rate structure produces the same total revenue as is derived from group C on the basis of the HMO's standard rate structure.

The above described approach also may be used in the case when an HMO bases its group rates on a defined per member per month rate standard (*i.e.*, $30). Assuming the $40 per employee contribution and the data given below for group D, three-tiered HMO rates may be established as follows:

| Type of Contract | Number of Subscriber Units | Average Contract Size | Prepaid Rate |
|---|---|---|---|
| Single | 30 | 1 | $40 |
| 2 party | 20 | 2 | x |
| 3+ party | 50 | 3.6 | 1.5x[13] |
| | 100 | 2.5 | |

---

[13] An arbitrarily determined relationship.

Given the $30 per member per month requirement, x (the 2 party rate) may be solved according to the following equation:

$$[.30 (\$40) + .20 (x) + .50 (1.4x] \div 2.5 = \$30.$$

$$x = \$66.32$$

The three-tiered rates of $40 (single subscriber), $66.32 (2 party), and $99.48 (3+ party) produce an average revenue yield of $30 per member per month from group D.

An HMO which establishes rates on the basis of a defined per subscriber per month standard (e.g., $72.60) also may use the approach. The rates of $40 (single subscriber), $63.79 (2 party) and $95.68 (3+ party) yield an average of $72.60 per subscriber per month from group D.

Example b Rate-setting which takes into account the rate-step relationships (loading factors) of competing alternate carrier plans:

An HMO may want, for competitive or other reasons, to alter the ratio relationships between rate-steps to conform with those of the alternate carrier. This is permissible under community rating.

Suppose, for example, that the HMO's standard three-tiered community rates are $33.41 (single subscriber), $66.82 ( 2 party), and $100.23 (3+ party). Note that the 2 party and 3+ party rates are, respectively, twice and three times the single subscriber rate.

The HMO may desire to establish rates for group C which have a step relationship of 1:2:2.5 (the rate-step relationship of the alternate carrier plan). The rates shown below, bearing this relationship, generate substantially the same total revenue on behalf of group C as do the standard rates. (Refer also to example a of Section B-1.)

| Contract | Number of Subscriber Units | Premium Rate | Total Revenue |
|---|---|---|---|
| Single | 38 | $37.40 | $1,421.20 |
| 2 party | 18 | 74.80 | 1,346.40 |
| 3+ party | 44 | 93.50 | 4,114.00 |
| | 100 | | $6,881.60 |

Example c Rate-setting which takes into account difference in family composition:

An HMO may alter the ratio relationships between rate steps to take into account unique family composition characteristics of individual groups.

For example, assume that group E has a disproportionately large number of single subscribers and that the HMO wants to establish three-tiered rates that are relatively more attractive to subscribers with large families. Assume, moreover, that the HMO's standard three-tiered community rates are those given in example b, above. Group E has 60 single subscribers, 20 2 party subscribers, and 20 3+ party subscribers. The rates given below produce the same total revenue on behalf of group E as do the standard rates.

| | |
|---|---|
| Single | $35.64 |
| 2 party | 71.28 |
| 3+ party | 89.10 |

3. Variations based on differences in contract effective dates

It is permissible under community rating for an HMO to apply the same increase in standard rates to all groups as their contracts renew during the calendar year. In this case, there will be times (e.g., March) when some groups (e.g., those with April-December renewal dates) would be charged the preceeding year's rates while other groups (e.g., those with January-March renewal dates) would be charged the new rates.

Alternatively, an HMO may charge different premium rates to groups which have the same benefits but which have different contract effective dates. Such differences may be justified to account for the effects, over time, of inflation or other factors which increase the HMO's costs. Under one approach, groups with later contract renewal dates would pay higher rates than groups with earlier contract renewal dates for the duration of their contracts. The following hypothetical schedule of rates is an example:

| | Rates, by period of contract renewal | | | |
|---|---|---|---|---|
| Type of Contract | 1st Quarter | 2nd Quarter | 3rd Quarter | 4th Quarter |
| Single | $25 | $26 | $27 | $28 |
| 2 party | 50 | 52 | 54 | 56 |
| 3+ party | 75 | 78 | 81 | 84 |

There are no Federal restrictions on how frequently such rates may be changed nor on the length of the contract period for which they apply.

### 4. Prepaid rate variations based on differences in the size of groups

The subpart A regulations allow nominal differentials in rates to reflect differences in marketing costs and the different administrative costs of collecting payments from three categories of subscribers:

(1) Non-group subscribers
(2) Small groups of 100 subscribers or less
(3) Groups of over 100 subscribers

Since rates are set prospectively, an HMO may not always know at the time an offering is made to a group, whether the number of resulting subscribers will constitute a small group or a large one. If rates are set in anticipation of a small group but a large one results from the offering, the HMO may charge the offered rates for the full effective period of the subscriber contract, provided that, upon subsequent offer of re-enrollment the rates are corrected to reflect actual group characteristics.

The guideline for nominal differentials is that, for the same effective dates, benefits and copayments, rates for small groups should not exceed 105% of large group rates, and non-group rates should not exceed 110% of large group rates, unless it can be demonstrated by the HMO that higher figures are warranted.

### 5. Community rating of copayments

The subpart A requirement that basic health services copayments be community rated will be considered met if copayments are applied uniformly as to amounts and limits to all subscribers with the same prepayment rates, service benefits, and effective dates of coverage.

## PHS/OHMO - § 110.105(b)(3)(ii)(C) - community rating: rate differentials

(ii) Differentials in rates may be established for subscribers enrolled in a HMO: (A) Under a contract with a governmental authority under section 1079 ("Contracts for Medical Care for Spouses and Children: Plans") or section 1086 ("Contracts for Health Benefits for Certain Members, Former Members and their Dependents") of Title 10 ("Armed Forces"), United States Code; or (B) under any other governmental program (other than the health benefits program authorized by chapter 89 ("Health Insurance") of Title 5 ("Government Organization and Employees"), United States Code; or (C) under any health benefits program for employees of States, political subdivision of States, and other public entities.

Q. Must the rates established for HMO contracts for basic and supplemental health services for employees of States, political subdivisions of States, or other public entities be based on a community rating system?

A. No.

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Q. Must the rates established for subscribers enrolled in an HMO under the health benefits program authorized by Chapter 89 ("Health Insurance") of Title 5 ("Government Organization and Employees"), United States Code be based on a community rating system?

A. Yes.

--------

Q. If a public entity were to establish an HMO for its employees, as well as other groups, would that HMO be exempt from applying the community rating standard to all its member groups?

A. No. A qualified HMO sponsored by a public entity is still required to use the community rating standard for those groups not exempted by Section 110.105(b)(3)(ii). However, the HMO need not use the community rating standard for the employees of the public entity.

## PHS/OHMO - § 110.105(c)(1) - postponement of the community rating requirement

(c) *Exceptions to community rating requirement.* (1) In the case of an HMO which provided comprehensive health services on a prepaid basis before it became a qualifed HMO, the requirement of community rating shall not apply to the HMO during the forty-eight month period beginning with the month following the month in which it became a qualifed HMO.

Q. What HMOs are entitled to postpone the requirement of community rating?

A. The legislative history concerning the postponement of the community rating requirement for 48 months indicates that its purpose was to avoid placing an unreasonable burden on existing plans which would otherwise have to deal with the complexities of altering their rating systems at the time of Federal qualification. To be eligible to postpone the application of the community rating requirement, an HMO must provide evidence to the Secretary of numbers of members and months of operation at the time of qualification, the combination of which indicates that the entity was a bona fide provider of comperhensive health services prior to qualification.

## PHS/OHMO - § 110.105(d) - other insurance

(d) *Charges for benefits covered by workers' compensation law or insurance policy.* The requirements respecting the basic health services payment do not apply to the provision of basic health services to a member for an illness or injury for which the member is entitled to benefits under a workers' compensation law or an insurance policy, but only to the extent these benefits apply to these services.

(1) For the provision of services for an illness or injury for which a member is entitled to benefits under a workers' compensation law, the HMO may, if authorized by this law, charge or authorize the provider of the services to charge, in accordance with the charges allowed under the law: (i) The insurance carrier, employer, or other entity which under the law is to pay for the provision of the services, or (ii) the member, to the extent that the member has been paid under the law for the services.

(2) For the provision of services for an illness or injury for which a member is entitled to benefits under an insurance policy, an HMO may charge or authorize the provider of the services to charge: (i) The insurance carrier under the policy, or (ii) the member, to the extent that the member has been paid under the policy for the services.

Q. Is it allowable for an HMO to refuse to provide basic health services when a member is entitled to benefits for such services under a worker's compensation law or an insurance policy?

A. No. The HMO must provide the services. However, the HMO may collect from a third party which is responsible for payment under a worker's compensation law or under an insurance policy, or from the member, if the member has been paid under the law or the insurance policy

## PHS/OHMO - § 110.108(a)(1)(i), (ii), (iii) - fiscally sound operation

**§ 110.108 Organization and operation.**

(a) *Fiscally sound operation and administrative and managerial arrangements.* (1) Each HMO shall have a fiscally sound operation as demonstrated by:

(i) Total assets being greater than total unsubordinated liabilities. In this evaluation, loan funds awarded or guaranteed under section 1305 of the Act are not included as liabilities, and if the funds have not been disbursed to the HMO by the Secretary or by an escrow agent, they are not included as assets;

(ii) Sufficient cash flow and adequate liquidity to meet obligations as they become due;

(iii) A net operating surplus. If the HMO has not earned a cumulative net operating surplus during the three most recent fiscal years, did not earn a net operating surplus during the most recent fiscal year, does not a have positive net worth, or is seeking a Federal loan or loan guarantee under sections 1305 or 1305A of the Act, the HMO shall submit a financial plan satisfactory to the Secretary to achieve net operating surplus within available fiscal resources. This plan shall include:

(A) A detailed marketing plan;

(B) Statements of revenue and expense on an accrual basis;

(C) Sources and uses of funds' statements; and

(D) Balance sheets;

Q. Is it allowable for an HMO to contract with an other party to direct the performance of the HMO's marketing functions?

A. Yes. An HMO is allowed to enter into a contract with an other party which undertakes marketing activities on the HMO's behalf; however, such contract must specify that the HMO retains the right to terminate the agreement and implement, at any time, its own marketing activities to any groups or individuals it proposes to serve. Further, the contract must assure that performance by the contractor under the contract will not be inconsistent with the HMO's compliance with its assurances and applicable requirements, such as the one for full and fair disclosure to members prior to enrollment.

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Q. Is it allowable for an other party to guarantee enrollment for HMO services?

A. Yes.

## PHS/OHMO - § 110.108(a)(1)(iv) - approach to the risk of insolvency

**(iv) A plan for handling insolvency which allows for continuation of benefits for the duration of the contract period for which payment has been made, continuation of benefits to members who are confined on the date of insolvency in an inpatient facility until their discharge, and payments to unaffiliated providers for services rendered;**

Q. What is meant by "unaffiliated providers?"

A. For purposes of this section, an unaffiliated provider is a provider who is not (a) a member of the HMO's staff or associated with its contracting medical group(s) or IPA(s); (b) a health professional under a direct services contract with the HMO; or (c) an entity, such as a hospital, with which an HMO has an arrangement for the provision of basic health services.

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Q. In Section 110.108(a)(1)(iv), what services are referred to in "services rendered?"

A. "Services rendered" means basic and supplemental health services rendered which were authorized by the HMO and for which it has an obligation to pay.

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Q. Are there limitations on the sources from which an HMO may secure insurance against the risk of insolvency?

A. No. The regulations do not limit the sources from which an HMO may obtain insolvency protection.

## PHS/OHMO - § 110.108(a)(1)(vi) - HMO liability insurance

> **(vi) Insurance policies or other arrangements, secured and maintained by the HMO and approved by the Secretary to insure the HMO against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks; and**

Q. What arrangements satisfy the requirement that the HMO be insured, or have other arrangements to protect against, losses arising from professional liability claims?

A. The following are acceptable approaches:

1. An HMO may obtain malpractice insurance in amounts adequate to protect itself against reasonably anticipated judgments.
2. An HMO may self-insure, in which case it must demonstrate sufficient unrestricted assets to pay reasonably anticipated judgments.
3. An HMO may obtain a "hold harmless" and indemnification agreement from the entities providing basic and supplemental health services, if such entities maintain adequate insurance or self-insurance to cover reasonably anticipated judgments.
4. Where state law specifically excludes an HMO from malpractice liability, no coverage is required.

## PHS/OHMO - § 110.108(a)(2)(i) and (ii) - administrative and managerial arrangements

(2) Each HMO shall have administrative and mangerial arrangements satisfactory to the Secretary, as demonstrated by at least the following:

(i) A policymaking body which exercises oversight and control over the HMO's policies and personnel to assure that management actions are in the best interest of the HMO and its membership; and

(ii) Personnel and systems sufficient for the HMO to organize, plan, control and evaluate the financial, marketing, health services, quality assurance program, administrative and management aspects of the HMO. At a minimum, the HMO shall be managed by an executive whose appointment and removal are under the control of the HMO's policymaking body.

Q. May another party retain the right to approve an HMO's underwriting rules and changes to the subscriber contracts and premium rates?

A. No. The HMO is required to retain the final exclusive approval authority to determine underwriting rules, premium rates, and subscriber contract provisions.

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Q. Must the Executive Director's position and reporting access to the HMO's policymaking body be formalized in writing?

A. Yes. Further, it is expected that the Executive Director's position and reporting access are established in the by-laws of the HMO to the extent that this is consistent with State law.

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Q. May the Executive Director be subject to removal by any group or individual other than the HMO's policymaking body?

A. No.

## PHS/OHMO - § 110.108(b) - financial risk

> (b) *Financial risk.* Each HMO shall assume full financial risk on a prospective basis for the provision of basic health services, except that it may obtain insurance or make other arrangements: (1) For the cost of providing to any member basic health services the aggregate value of which exceeds $5,000 in any year;
>
> (2) For the cost of basic health services provided to its members other than through the HMO because medical necessity required their provision before they could be secured through the HMO; and
>
> (3) For not more than 90 percent of the amount by which its costs for any of its fiscal years exceed 115 percent of its income for that fiscal year.

Q. Except as specifically authorized, is it allowable for an HMO to transfer its financial risk for the provision of health services to non-providers of health services?

A. No. An HMO is not authorized to transfer any or all of that required risk to non-providers.

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Q. Is it allowable for an HMO to transfer its required risk to its providers of service?

A. Yes. The HMO entity may transfer all, or some, of the financial risk of providing health services for its members to its providers of service. However, under such arrangements, the HMO or the providers may not insure or make other arrangements, except in accordance with Section 110.108(b)(1), (2), and (3). Further, the HMO entity must provide evidence of its ability to maintain its fiscal soundness under any risk-sharing arrangement.

## PHS/OHMO - § 110.108(c) - broadly representative enrollment

(c) *Broadly representative enrollment.* After full and fair disclosure of its benefits, coverage, rates, grievance procedures, location, and hours of service, and a general description of its participating providers and financial condition, each HMO shall offer enrollment to persons who are broadly representative of the various age, social, and income groups within its service area. In the case of an HMO which has a medically underserved population located in its service area, not more than 75 percent of the HMO members may be enrolled from the medically underserved population unless the area in which that population resides is also a rural area.

Q. Are there additional regulations regarding full and fair disclosure to coordinate with requirements under the Employee Retirement Income Security Act of 1974 (ERISA)?

A. No. The Secretary has proposed to amend the regulations regarding full and fair disclosure by an HMO to members and employers to coordinate with ERISA. Until those provisions are published as final rules, the regulations at Section 110.108(c) are unchanged.

## PHS/OHMO - § 110.108(d)(1), (2), (3) and (4) - open enrollment

(d) *Open enrollment.* If the HMO has either provided comprehensive health services on a prepaid basis for a period of at least 5 years or has an enrollment of at least 50,000 members, it shall have an open enrollment period at least once during the fiscal year next following each fiscal year in which it did not have a financial deficit. (For purposes of this paragraph, financial deficits must be reported and certified by an independent Certified Public Accountant.) The period of open enrollment shall be determined under paragraph (d)(1) of this section. During open enrollment, the HMO shall accept individuals for membership in the order in which they apply for enrollment and, except as provided in paragraph (d)(2) of this section, without regard to preexisting illness, medical condition, or degree of disability.

(1) An open enrollment period for an HMO shall be the lesser of—

(i) 30 days, or

(ii) The number of days in which the organization enrolls a number of individuals at least equal to 3 percent of its total net increase in enrollment (if any) in the fiscal year preceding the fiscal year in which the open enrollment period is held. In determining the total net increase in enrollment in an HMO, the HMO need not include any individual who is (A) enrolled in the HMO through a group which had a contract or other arrangement for health care services with the HMO when the HMO was determined to be a qualified HMO, or (B) entitled to insurance benefits under Title XVIII of the Social Security Act or to medical assistance under a State plan approved under Title XIX of that Act and was enrolled in the HMO when the HMO was determined to be a qualified HMO.

(2) An HMO is not required to enroll individuals who are confined to an institution because of (i) chronic illness, (ii) permanent injury, or (iii) other infirmity which would cause economic impairment to the HMO, as demonstrated to the satisfaction of the Secretary, if these individuals were enrolled.

(3) And HMO may defer the effective date of benefits for individuals enrolled under this paragraph for up to 90 days after the date of enrollment.

(4) An HMO may require an individual applying for membership at periods other than the required annual open enrollment period to submit to and pay for a health status questionnaire or a health examination. An HMO may deny enrollment based on results of this questionnaire or health examination.

Q. If an HMO determines that a member falsified information on a health questionnaire prior to enrollment, is it allowable for the HMO to expel such member?

A. Neither the Act nor the regulations prohibit an HMO from expelling a member for material falsification of information of health questionnaires, e.g., relating to health status.

## PHS/OHMO - § 110.108(g) - conversion of membership

(g) *Conversion of membership.* Each HMO shall offer membership on the same terms and conditions as are available to a nongroup subscriber to:
(1) Each subscriber (and his enrolled dependents) leaving a group; and
(2) Each member who would otherwise cease to be eligible for HMO membership because of his or her age or the death or divorce of a subscriber.

Q. If an HMO does not offer individual (non-group) enrollment except as required under open enrollment provisions, must it offer conversion to non-group status to members leaving a group?

A. Yes. The regulations require that the HMO offer each subscriber leaving a group the opportunity to convert his/her membership to non-group status. Therefore, even if the HMO does not otherwise offer enrollment to individuals, the HMO must offer membership to individuals terminating their group membership.

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Q. May the HMO require that a member be enrolled for a minimum period of time before (s)he is eligible to convert to non-group membership?

A. No. An HMO may not impose a minimum length of time of membership before permitting group members to convert to a non-group status.

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Q. For purposes of Section 110.108(g), what is the definition of "group?"

A. For the purposes of this section, a group consists of members who enroll in the HMO through a contract or other arrangement which provides for the enrollment of two or more subscribers.

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Q. Are HMO members entitled to conversion privileges when the subscriber member retires?

A. Yes. Subscribers and their enrolled dependents are eligible for non-group membership in the HMO when the subscriber employee retires.

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continued on next page ...

**(g) *Conversion of membership.* Each HMO shall offer membership on the same terms and conditions as are available to a nongroup subscriber to:**

**(1) Each subscriber (and his enrolled dependents) leaving a group; and**

**(2) Each member who would otherwise cease to be eligible for HMO membership because of his or her age or the death or divorce of a subscriber.**

Q. Must an HMO offer a Medicaid recipient enrolled in the HMO the option of converting to a non-group membership within the HMO if he leaves the Medicaid group?

A. Yes. A Medicaid recipient, like a member of any other group, can convert to non-group membership if he/she leaves the group, provided the group contract with the HMO is still in effect. Under the provisions of full and fair disclosure, the HMO must inform an enrollee of this opportunity. (See Section 110.108 (c).)

If the former Medicaid recipient does elect to convert his membership to non-group membership, he must initiate his re-enrollment and be responsible for the premium payments.

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Q. Is it permissable for the HMO to require members who reach age 65 to convert from group to non-group status as a condition of continued membership?

A. No. There has been some confusion about the conversion of membership provision of Section 110.108(g) due to a statement added to Section 110.108(f) indicating that an HMO may require, as a condition of membership, that dependents of a subscriber, upon reaching a specified age, convert to non-group membership. This reference to age applies to children or minors who cease to meet the HMO's requirement for eligibility as an employee's dependents. It does not apply to subscribers or their eligible dependents who reach age 65.

## PHS/OHMO - § 110.108(h)(1)(i) and (ii) - policymaking body

(h) *Policymaking body.* (1) In the case of a private HMO, no later than one year after becoming operational as a qualified HMO, at least one-third of the membership of its policymaking body must be members of the HMO who reside in or in proximity to the service area of the HMO. An HMO with regional components and one overall policymaking body must assure that the individuals satisfying the one-third member requirement reside in, or in proximity to, the service area of at least one of the HMO's regional components. HMOs with policymaking bodies consisting of the same individuals must assure that the individuals satisfying the one-third member requirement reside in, or in proximity to, the service area of at least one of the HMOs.

(i) No member having ownership of or financial interest in, or employed by, or gaining financial reward from direct dealings with, the HMO or a plan-affiliated institution or organization, and no members of the immediate family of such member shall be included in the minimum one-third member representation on the policymaking body. However, none of the foregoing prohibits the payments of directors' fees or other similar fees, or interest and dividends derived from membership in an HMO cooperative, to persons serving on the policymaking body.

(ii) There shall be equitable representation on the member portion of the policymaking body of members from the medically underserved populations served by the HMO in proportion to their enrollment relative to the entire enrollment; except that if the membership from these medically underserved populations is at least 5 percent of the total enrollment, then those populations shall not be without representation.

Q. May the non-member portion of the policymaking body consist of individuals who are appointed by, employed by, serve on the board of, or serve as representatives of an organization which sponsors the HMO or is an insuring organization which competes with the HMO for enrollment?

A. Yes.

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Q. Is the requirement that the medically underserved population be represented satisfied if the membership of the policymaking body of the HMO is elected at large by the enrolled population?

A. Not necessarily. If the HMO's approved service area encompasses areas which the Secretary has designated as medically underserved areas (MUAs), and if at least five percent of the HMO's total enrollment resides in such MUAs, then HMO "members from medically underserved populations" must be represented on the HMO's policymaking body by persons specifically identifiable as representatives of that class.

## PHS/OHMO - § 110.108(i) - grievance procedures

(i) *Grievance procedures.* Each HMO shall have and use meaningful procedures for hearing and resolving grievances between the HMO (including the staff of the HMO, the medical group, and the IPA) and the members of the HMO. These procedures must assure that: (1) Grievances and complaints will be transmitted in a timely manner to appropriate decisionmaking levels within the HMO which have authority to take corrective action; and (2) appropriate action will be taken promptly, including a full investigation if necessary and notification of concerned parties as to the results of the HMO's investigation.

Q. Must grievance procedures be in writing and readily accessible to HMO members?

A. Yes. Written and readily accessible grievance procedures are required to assure their full and fair disclosure to members (See also Section 110.110(c) for a reference to requirements regarding Medicare and Medicaid enrollees).

## PHS/OHMO - § 110.108(m) and (n) - health education and medical social services

(m) *Health education.* In support of the provision of health services, each HMO shall actively provide its members:

(1) Health education services including instruction in personal health care measures;

(2) Information about its services, including education on generally accepted medical standards for use and frequency of its services; and

(3) Nutritional education and counseling;

(n) *Medical social services.* In support of the provision of health services, each HMO shall offer its members medical social services, which shall include appropriate assistance in dealing with the physical, emotional and economic impact of illness and disability. These services may include pre- and post-hospitalization planning, referral to services provided through community health and social welfare agencies, and related family counseling;

Q. Must the HMO provide health education and medical social services through its staff, medical group(s), or IPA?

A. No. Health education and medical social services need not be provided by staff, medical group, or IPA providers. An HMO may provide or arrange for these services through agreements with appropriate personnel.

# SECTION V

## Guidance Papers

Guidance papers to follow.

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